EXHIBIT A

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IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

TEVA PHARMACEUTICALS USA, INC., Plaintiff, v. CORCEPT THERAPEUTICS, INC., AND OPTIME CARE INC., Defendants.	Case No. 5:24-cv-03567-NW **THIRD AMENDED AND SUPPLEMENTAL COMPLAINT** **DEMAND FOR JURY TRIAL**

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I. INTRODUCTION

1. Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") brings this action against Defendants Corcept Therapeutics, Inc. ("Corcept"), Optime Care Inc. ("Optime"), and Curant Health LLC ("Curant," and together with Corcept and Optime, "Defendants"), for pervasive and highly damaging antitrust violations that have thwarted Teva's ability to compete with Corcept and, in turn, have deprived vulnerable patients of access to lower-cost generic treatments for the debilitating disease from which they suffer. Teva and Corcept are rival pharmaceutical manufacturers. Optime and Curant are specialty pharmacies that distribute Corcept's only product and are contractually forbidden from distributing any competing products. Together, these Defendants have been engaged in an ongoing scheme to monopolize the market for Korlym (mifepristone), a cortisol receptor blocker indicated to treat endogenous Cushing's syndrome.

2. In 2012, Corcept received FDA approval to launch its only branded drug, Korlym, for the treatment of certain patients with endogenous Cushing's syndrome. Cushing's syndrome is a rare, debilitating disease affecting approximately 20,000 patients in the United States. For this highly vulnerable patient population, Cushing's syndrome has a direct, severe impact on quality of life. Its symptoms include abnormal weight gain, a fatty hump between the shoulders, wide purple stretch marks, increased fat around the base of the neck, weak muscles, and easy bruising, among other things. It can also cause many significant health problems, including heart attacks and strokes, blood clots in the legs and lungs, depression, memory loss, type 2 diabetes, bone loss and fractures, and a range of infections, among other serious complications. It can be fatal if left untreated, with some patients having a life expectancy of less than five years without treatment.

3. Korlym was the only FDA-approved treatment for endogenous Cushing's syndrome. Korlym is a once-a-day pill that is extremely cheap to produce, but Corcept has taken advantage of its lone position in the market to charge supracompetitive prices—several hundred thousand dollars or more for a year's supply—in the decade-plus that Corcept has enjoyed monopoly power.

4. Teva sought to break Corcept's monopoly in 2017, when Teva filed an Abbreviated New Drug Application ("ANDA"), seeking FDA approval to bring a more affordable generic version of Korlym to the market. Defendants have engaged in a multipronged scheme to prevent

that from happening, including through the wide variety of unlawful means that are the subject of this lawsuit.

5. In the years since Teva filed its generic Korlym ANDA, and continuing to this day, Defendants have engaged in a multifaceted scheme to prolong Corcept's monopoly by stifling competition from Teva at every turn. To start, Corcept knowingly, improperly, and fraudulently manipulated the patent system to delay FDA approval of Teva's generic product by ***years***, and abused the courts through sham litigations that served no purpose but to forestall competition from Teva. Corcept and Optime also entered into an unprecedented exclusive-dealing agreement that requires Optime to distribute Corcept's brand Korlym product but expressly forbids it from distributing any competing products, including Teva's generic, thereby blocking Teva's access to the key distribution channel and cutting off patients from accessing Teva's lower-priced generic product. Corcept recently sought to entrench its monopoly further by entering into a similarly anticompetitive exclusive-dealing agreement with Curant. Lastly, Corcept has engaged in a long-running campaign to pay bribes and kickbacks to physicians as compensation for continuing to prescribe brand-name Korlym, notwithstanding the availability of Teva's lower-cost generic.

6. Corcept has all but admitted the key components of this scheme. For example, on one earnings call, Corcept's CFO admitted that Corcept sued Teva for infringing patents that do not have "a direct read" or any "express connection" to Korlym's FDA-approved label or Teva's proposed generic label. These remarks make plain (1) that Corcept subjectively understood that it never should have listed those patents in the FDA's Orange Book, and (2) that its subsequent patent infringement litigation was not pursued in good faith, but instead was a bad-faith sham, the only objective of which was to delay competition from Teva for years, buying Corcept more time as a monopolist so that it could continue exploiting vulnerable patients by charging supracompetitive prices.

7. Similarly, Corcept's SEC filings confirm that its exclusive arrangement with Optime is a long-term, perpetually-renewing agreement that expressly forbids Optime from working with Corcept's competitors, and that Optime is not free to terminate this arrangement even if a company

like Teva offers it a better deal. On an earnings call, Corcept's President of Endocrinology confirmed that this highly unusual exclusive-dealing arrangement has succeeded in erecting substantial "barriers to generic adoption," by blocking by far the most effective distribution channel Teva could otherwise use to reach patients and threaten Corcept's dominant market share. Corcept's President of Endocrinology has even brazenly boasted that the company's exclusive agreement with Optime has allowed Defendants to circumvent a host of state "automatic substitution" laws that are designed to protect patients by requiring or encouraging pharmacists to dispense lower-priced generic drugs in place of higher-priced brand drugs. Thanks to its exclusive scheme with Optime, Corcept's executive gloated, Corcept has ensured that "automatic substitution does not happen ... like you see in a lot of these cases" after a more affordable generic drug becomes available. Corcept's recent agreement with Curant is designed to, and will, perpetuate these anticompetitive effects to an even greater extent.

8. Corcept has further entrenched its monopoly by paying physicians illicit bribes and kickbacks to induce them to prescribe brand Korlym, notwithstanding the availability of Teva's lower-priced generic—which has stifled competition and robbed vulnerable patients and their health plans of the opportunity to choose Teva's lower-priced generic in place of Corcept's more expensive brand product. These allegations are supported by publicly available payment and prescription data, well-sourced allegations in a federal securities lawsuit against Corcept, reporting by investigative journalists, and an ongoing investigation into Corcept by the United States Attorney's Office for the District of New Jersey.

9. Defendants' multipronged scheme has been remarkably effective—and remarkably damaging, with Teva and patients ultimately paying the price. Teva launched its generic product approximately two years ago, but during that time Teva has captured almost no market share—less than 4% of the market—despite offering a product that is identical to brand Korlym and materially less expensive. In the words of Corcept's own President of Endocrinology on May 1, 2024, almost three-and-a-half months after Teva's generic product launched, Corcept was "not aware of losing any patients to generic mifepristone." And on July 29, 2024—more than six months after Teva

launched—Corcept's President of Endocrinology re-affirmed that "[t]he Teva product has been available in the channel for many months, so it's out there, but it has had very little impact on our business."

10. These results are unheard-of and would be impossible to explain in a functioning, competitive pharmaceutical market, where generic drugs typically capture 60-75% of the market or more in their first six months, and patients enjoy the benefits of robust competition and lower prices. As a result, Teva has been deprived of substantial revenue, and vulnerable patients have been forced to continue paying supracompetitive prices for Corcept's brand product when an identical—and more affordable—generic option is available, but inaccessible, thanks to Defendants' ongoing anticompetitive scheme.

11. The antitrust laws do not tolerate this state of affairs. Judicial intervention is necessary to remedy the substantial damages Teva has already suffered, and to restore competition to the market for Korlym, so that Teva can compete on a level playing field going forward and patients can enjoy the benefits of lower-priced generic drugs as Congress intended.

II. PARTIES

A. Plaintiff

12. Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") is a pharmaceutical manufacturer organized and existing under the laws of Delaware with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

B. Defendants

13. On information and belief, Defendant Corcept Therapeutics, Inc. ("Corcept") is a pharmaceutical manufacturer organized and existing under the laws of Delaware with its principal place of business at 149 Commonwealth Drive, Menlo Park, California 94025.

14. On information and belief, Defendant Optime Care Inc. ("Optime") is a specialty pharmacy organized and existing under the laws of Delaware with its principal place of business at 4060 Wedgeway Court, Earth City, Missouri 63045.

15. On information and belief, Defendant Curant Health Georgia LLC ("Curant") is a specialty pharmacy organized and existing under the laws of Delaware with its principal place of business at 200 Technology Ct. SE STE B, Smyrna, GA 30082.

III. JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction over the federal law claims alleged in this action pursuant to 28 U.S.C. § 1331 and 28 U.S.C. § 1337, as this action arises under the antitrust laws of the United States, including Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26.

17. This Court has subject matter jurisdiction over the state law claims alleged in this action pursuant to 28 U.S.C. § 1367, as the state law claims are so related to the federal law claims as to form part of the same case or controversy. Such supplemental or pendent subject matter jurisdiction will also avoid unnecessary duplication and multiplicity of actions, and should be exercised in the interests of judicial economy, convenience, and fairness.

18. The actions complained of occurred in, and substantially affected, interstate commerce. Specifically, Defendants are engaged in interstate commerce and in activities substantially affecting interstate commerce. Defendants' conduct alleged herein has a substantial effect on interstate commerce. Defendants market and sell Korlym in interstate commerce, in all states and territories of the United States. Patients across the country purchase Corcept's drug product, Korlym.

19. Corcept may be found in, transacts business in, is headquartered in, and is subject to personal jurisdiction in, the Northern District of California.

20. Optime transacts business in, and is subject to personal jurisdiction in, the Northern District of California, by virtue of marketing and sales activities that purposefully and deliberately target consumers of Korlym (including health plans and patients) in California.

21. The violations of law alleged in this Complaint took place, in part, and have injured Teva in this judicial district. Venue is therefore proper in the Northern District of California pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391.

IV. REGULATORY BACKGROUND

22. Federal drug laws "reflect an attempt to balance two competing interests: [p]romoting competition between 'brand-name' or 'innovator drugs' and 'generic' drugs, and encouraging research and innovation."[1] As a compromise between these goals, Congress enacted the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act, in 1984.[2]

23. Federal patent law and the Hatch-Waxman Act provide exclusivity periods to incentivize brand drug makers to innovate and develop new drugs. At the same time, the Hatch-Waxman Act streamlines the generic drug approval process and creates incentives for generic manufacturers to come to market as quickly as possible. Congress wanted to encourage the speedy approval of generic drugs because the entry of generic drugs into the market produces enormous cost savings to patients and health insurers.

24. When pharmaceutical markets operate under competitive conditions as intended by Congress, the market switches rapidly from the brand to a lower-priced generic when the lower-priced generic becomes available. Patients benefit in the form of substantial savings and increased access to affordable medicines, while generic manufacturers benefit in the form of revenue and market share.

25. Corcept understood that the market for Korlym would be no exception to these competitive dynamics. To prolong its monopoly and combat the risk of losing profits and market share to Teva's lower-priced generic product, Corcept resorted to a multitude of unlawful tactics to stifle competition and keep prices high, including knowingly listing ineligible patents (which it knew and publicly admitted did not even cover Korlym) in the FDA's Orange Book, engaging in sham patent litigation, entering into an anticompetitive exclusive-dealing arrangement with Optime (and later Curant) to choke off the only effective distribution channel, and making illicit payments to physicians to ensure they continue prescribing brand Korlym.

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[1] Patent Submission and Listing Requirements, 68 Fed. Reg. 36676-01, 36676 (June 18, 2003).

[2] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

A. The Regulatory Process for Approval of New Drugs

26. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, the United States Food and Drug Administration ("FDA") must approve a new drug before it can be sold on the market.[3] To obtain FDA approval for a new brand-name drug, a manufacturer must file a New Drug Application ("NDA") that includes certain specified information, including examples of the proposed label for the drug and any patents that claim the drug substance (active ingredient), drug product (formulation or composition), or a method of using the drug for which approval is sought in the NDA.[4]

27. Under the Hatch-Waxman Act, brand drug companies receive periods of "regulatory exclusivity" to protect intellectual property rights and encourage innovation through new drug development.[5]

28. "The FDA publishes the names of approved drugs and their associated patent information in the *Approved Drug Products with Therapeutic Equivalence Evaluations* list, commonly referred to as the 'Orange Book.'"[6]

29. The Hatch-Waxman Act and FDA regulations require brand manufacturers to publish information about the patents that cover their drugs in the Orange Book, so that prospective competitors—including generic drug manufacturers—can understand the scope of a brand drug's ostensible patent protection.[7] Accurate Orange Book information promotes competition by allowing generic companies to "assess the intellectual property assertions related to an NDA holder's product that could potentially block entry of their proposed ... generic drug product."[8]

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[3] 21 U.S.C. § 355(a).

[4] *Id.* § 355(b)(1)(A)(vi), (viii).

[5] Cong. Rsch. Serv., *The Role of Patents and Regulatory Exclusivities in Drug Pricing* (Jan. 30, 2024), https://crsreports.congress.gov/product/pdf/R/R46679.

[6] *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1045 (Fed. Cir. 2010).

[7] 21 U.S.C. §§ 355(b)(1)(A)(viii), (c)(2); 21 C.F.R. § 314.53(b)(1).

[8] Listing of Patent Information in the Orange Book, 85 Fed. Reg. 33169-01, 33172 (June 1, 2020).

30. Under federal law, only certain types of patents are permitted to be listed in the Orange Book. To be eligible for listing in the Orange Book, a patent must claim the drug for which the brand company submitted its NDA, and either the drug substance (active ingredient), the drug product (formulation or composition), or a method of using the drug for which approval is sought or has been granted in the NDA.[9] With respect to method-of-use patents, FDA regulations have long emphasized that "[i]f an NDA applicant or holder or patent owner intends to submit information on a patent that claims a method of use, the patent *must claim a use that is described in the NDA*. If we have already approved the NDA, the patent *must claim a method of use that is in the labeling of the approved NDA*."[10]

31. Listing a patent in the Orange Book gives brand manufacturers the power, by later suing for infringement of that same listed patent, to trigger an automatic delay of FDA approval of competing generic products for 30 months—regardless of whether the patent is valid or infringed, and regardless of whether the patent was properly listed in the Orange Book.[11]

32. The FDA does not review brand companies' Orange Book listings to ensure that their patents are eligible to be listed there. "[T]he FDA does not verify that submitted patents actually meet statutory listing criteria, nor does the FDA proactively remove improperly listed patents."[12] Rather, the FDA's "'duties with respect to Orange Book listings are purely ministerial,'" meaning the FDA simply lists patent information provided by brand companies without independently checking that a patent should be listed in the Orange Book.[13]

B. The Generic Drug Approval Process and Market Entry

33. When the exclusivity period for a brand drug expires, generic competitors may enter the market with lower-cost generic substitutes. The Hatch-Waxman Act created a streamlined

[9] 21 U.S.C. § 355(b)(1)(A)(viii).

[10] Patent Submission and Listing Requirements, 68 Fed. Reg. at 36681 (emphasis added).

[11] 21 U.S.C. § 355(j)(5)(B)(iii).

[12] *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 60 F.4th 1373, 1378 (Fed. Cir. 2023).

[13] *Id.*

process for approving generic drugs for entry into the market. Additionally, in certain circumstances the Hatch-Waxman Act grants the first generic entrant the exclusive right to sell a generic version (alongside the brand drug) for 180 days. This limited period of exclusivity further incentivizes generic entry and encourages generic manufacturers to challenge patents that are not infringed by a proposed generic product, which entails expensive and time-consuming litigation but can result in generic entry years earlier than the listed patents' expiration dates. As explained in more detail below, a first generic nearly always captures a large market share and drives down prices immediately upon entering the market. The resulting competition tends to dramatically reduce drug prices, saving health insurers and patients billions of dollars across the market every year.

1. The FDA's Generic Drug Approval Process

34. When a drug applicant seeks the FDA's approval to introduce a generic version of an approved drug, the drug applicant may file an Abbreviated New Drug Application ("ANDA").[14] An ANDA is a more streamlined submission than an NDA, because it allows the generic applicant to rely on the safety and efficacy information previously documented by a brand company if the generic company can demonstrate "bioequivalence" between its generic drug and the brand drug.[15]

35. The Hatch-Waxman Act permitted the submission of ANDAs, rather than full NDAs, as part of a deliberate and carefully constructed attempt to balance competing policy priorities in the pharmaceutical industry. On the one hand, Congress sought to encourage "pioneering research and development of new drugs," while on the other hand, "enabling competitors to bring low-cost, generic copies of those drugs to market."[16]

36. Before Congress passed the Hatch-Waxman Act, *all* drug makers—including generic drug manufacturers—had to submit full NDAs before marketing a drug, with extensive and costly

[14] 21 U.S.C. § 355(j).

[15] *Id.* § 355(j)(2)(A).

[16] *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (explaining that Congress authorized ANDAs, substantially shortening the time and effort needed to obtain marketing approval, to enable new drugs to be marketed more quickly and cheaply).

animal studies and human clinical trials. As a result, very few generic drugs had come to market prior to the Hatch-Waxman Act, because the costs and risks of bringing a generic drug to market often outweighed the benefits, particularly because generics sell for a fraction of the price of brand-name drugs and generate much smaller profits.[17]

37. The Hatch-Waxman Act therefore created Section 505(j)—a simplified, less expensive process by which generic drug manufacturers may seek approval of a new generic drug. Instead of submitting a full NDA, generic drug manufacturers may now submit an ANDA which requires only a showing that a proposed generic drug is bioequivalent to the reference listed brand drug. A bioequivalent drug shares the same method of administration, dosage, form and rate of absorption, and effects as the reference listed drug.[18] After establishing bioequivalence, the FDA permits the ANDA applicant to rely on the reference listed drug's clinical studies and trials for safety and efficacy data.[19]

38. As a result, generic versions of brand-name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand-name counterparts. Generic drugs meeting these standards receive an "AB rating." The only material difference between generic drugs and their corresponding brand-name versions is their price.

2. The Orange Book and the Generic Drug Approval Process

39. Under the Hatch-Waxman Act, generic manufacturers must follow certain procedures with respect to the Orange Book. During the ANDA application process, a generic manufacturer must include in its submission a certification addressing all of the patents that the brand drug company has listed in the Orange Book at the time the ANDA is filed.

40. An ANDA applicant must certify one of the following:

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[17] *See* Gary Owens, *Seizing the Opportunity*, 1 Am. Health Drug Benefits 3, 52-55 (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4115321/#R1 ("In 1984, only about 18.6% of all prescriptions in the United States were filled with generic medications.").

[18] 21 U.S.C. § 355(j)(2); 21 C.F.R. § 320.

[19] 21 U.S.C. § 355(j).

(i) No patents have been listed in the Orange Book.

(ii) The patents listed in the Orange Book have expired.

(iii) The generic manufacturer will not market its competing product until after the patents listed in the Orange Book expire.

(iv) The patents listed in the Orange Book are "invalid or will not be infringed by the manufacture, use, or sale" of the generic product.[20]

41. These certifications are known as Paragraph I, Paragraph II, Paragraph III, and Paragraph IV certifications, respectively.

42. Paragraph I, II, and III certifications do not threaten a brand company's current patent(s). However, because a Paragraph IV certification challenges the validity, enforceability, or infringement of a brand company's patent(s), the ANDA applicant must provide the brand company with notice of the Paragraph IV certification.[21]

43. In turn, the Hatch-Waxman Act deems a Paragraph IV certification to be a technical act of patent infringement, which gives subject matter jurisdiction to the courts and allows a brand manufacturer to immediately sue the generic manufacturer for patent infringement upon receiving notice of the generic company's Paragraph IV certification—even *before* the generic drug enters the market.[22] However, a brand manufacturer can only sue the generic applicant if it has a good faith basis to assert infringement.

44. If a brand company sues a generic company for patent infringement within 45 days of receiving notice of the generic company's Paragraph IV certification based upon a patent listed in the Orange Book at the time the ANDA is filed, FDA approval for the generic drug is automatically stayed for 30 months.[23] This 30-month stay remains in place unless the relevant patents expire or

[20] *Id.* § 355(j)(2)(A)(vii).

[21] *Id.* § 355(j)(2)(B).

[22] *Id.* § 355(j)(5)(B)(iii).

[23] *Id.*

the ANDA applicant succeeds in the infringement action (or the parties settle) before the 30-month period is over.[24]

45. When an ANDA otherwise meets the substantive requirements for approval, but cannot receive effective approval because of the 30-month stay or some form of exclusivity (*i.e.*, marketing exclusivity granted by the FDA), the FDA may grant the application "tentative approval."[25] To receive tentative approval, an ANDA must meet all of the requirements for approval generally; that is, the only barrier to outright approval must be the pendency of the 30-month stay or an exclusivity period.[26]

46. An ANDA that has received tentative approval is not approved, and the drug may not legally be marketed, until the FDA conducts any necessary additional review of the application, confirms that the application continues to meet the standards for final approval, and issues a letter granting the ANDA final approval.[27]

47. Receiving tentative approval does not guarantee that an ANDA will receive final approval. FDA regulations explain that the "FDA's tentative approval of a drug product is based on information available to FDA at the time of the tentative approval letter (*i.e.*, information in the ANDA and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to FDA's attention."[28] For example, it is common for generic drug companies to submit amendments to their ANDAs after receiving tentative approval. Such amendments can require new rounds of FDA review and approval before an ANDA is deemed eligible for final approval. For instance, if an applicant submits a standard amendment adding a new facility that will be involved in manufacturing the generic drug product, the FDA will classify that

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[24] *Id.*

[25] *Id.* § 355(j)(5)(B)(iv)(II)(dd)(AA); 21 C.F.R. § 314.107(b)(3)(v).

[26] 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA).

[27] *Id.* § 355(j)(5)(B)(iv)(II)(dd)(BB); 21 C.F.R. §§ 314.105(d), 314.107(b)(3)(v).

[28] 21 C.F.R. 314.105(d).

amendment as a major amendment requiring a preapproval inspection of the new facility, and will set a 10-month review goal for that amendment.[29]

3. Incentives for Generic Manufacturers to Enter the Market

48. In the Hatch-Waxman Act, Congress created a special incentive for generic drug companies to submit Paragraph IV certifications challenging brand companies' patents. Above all, the first generic company to submit an ANDA with a Paragraph IV certification for a given drug may receive the exclusive right to sell a generic version of the drug for 180 days.[30] This 180-day period begins when the generic company launches its product. During this 180-day period, the FDA is prohibited from approving other generic manufacturers' ANDAs. The only competition the first ANDA filer faces during this period is the brand manufacturer who, under its own NDA, may sell or license its own generic product (known as an "authorized generic"), in addition to continuing to sell the brand product.

49. The promise of this 180-day exclusivity period offers a strong incentive because during this time, a first generic typically captures a durable market share advantage. One study found that the first generic entrant has a market share advantage of 80% over the second generic entrant, and 225% over the third entrant over a three-year period of analysis.[31]

50. When pharmaceutical markets operate competitively—as Congress intended—generic drugs typically capture a large market share from the brand company immediately upon entering the market. That is in large part because generics are nearly always priced at a material discount compared to the brand product. One study found that first generics launch at an average list price discount of 18% compared to the brand, and that savings are even greater when considering net

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[29] *See generally* U.S. Dep't of Health & Human Servs., *ANDA Submissions—Amendments and Requests for Final Approval to Tentatively Approved ANDAs Guidance for Industry* (Jan. 2024), https://www.fda.gov/media/119718/download.

[30] *See* 21 U.S.C. §§ 355(j)(5)(B)(iv)(I), 355(j)(5)(B)(iv)(aa)-(cc), 355(j)(5)(D)(iii).

[31] Yu Yu & Saching Gupta, *Pioneering Advantage in Generic Drug Competition*, 8 Int'l J. Pharm. & Healthcare Mktg, vol. 8, no. 2 (2014), https://www.emerald.com/insight/content/doi/10.1108/IJPHM-11-2013-0063/full/html.

price, as first generics launch at net prices that are, on average, 30% less than the brand drug's net price.[32]

51. Furthermore, since the passage of the Hatch-Waxman Act, every state has adopted substitution laws that either require or permit pharmacies to substitute bioequivalent generic drugs for brand drug prescriptions, unless the prescribing physician specifically orders otherwise.[33]

52. At least 12 states and territories have mandatory generic substitution laws, which require pharmacists to substitute generic versions of prescribed drugs if all prescription requirements are met.[34]

53. At least 40 states and territories have permissive generic substitution laws, which permit pharmacists to substitute generic versions of prescribed drugs if all prescription requirements are met.[35]

54. Generic substitution laws can only operate as intended if the relevant pharmacy carries the generic version of the prescribed drug. Otherwise, the pharmacist has nothing to substitute, and must—of necessity—dispense the brand version despite the preference for lower-priced generics by Congress, state legislatures, patients, and health insurers.

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[32] Ass'n for Accessible Medicines, *Access Denied: Why New Generics Are Not Reaching America's Seniors*, at 7 (Sept. 2019), https://accessiblemeds.org/sites/default/files/2019-09/AAM-White-Paper-Access-Denied-First-Generics-web_0.pdf.

[33] Jesse C. Vivian, *Generic-Substitution Laws*, 33 U.S. Pharm. 30 (2008), https://www.uspharmacist.com/article/generic-substitution-laws; *see also* Alison Masson & Robert L. Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* (1985), https://www.ftc.gov/sites/default/files/documents/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection-laws/massonsteiner.pdf.

[34] These states and territories are Florida, Kentucky, Massachusetts, Minnesota, Mississippi, New Jersey, New York, Pennsylvania, Puerto Rico, Rhode Island, Washington, and West Virginia. *See* Jesse C. Vivian, *Generic-Substitution Laws*, 33 U.S. Pharm. 30 (2008), https://www.uspharmacist.com/article/generic-substitution-laws.

[35] These states and territories are Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Georgia, Guam, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Michigan, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oregon, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Wisconsin, and Wyoming. *See id*.

55. Thanks to generic substitution laws and other institutional features of pharmaceutical distribution and use, the pharmaceutical industry exhibits an economic dynamic in which the launch of bioequivalent generics results in rapid price declines and rapid sales shifts from brand to generic purchasing. In fact—assuming markets are functioning competitively—once a generic drug enters the market, it quickly captures sales of the corresponding brand drug, often capturing 60-75% or more of the market within the first six months, and usually more than 80% within the first year.[36]

56. These dynamics entail substantial savings for health plans and patients. A 2022 FDA study found that generic drug approvals in 2018, 2019, and 2020 resulted in savings of $17.8 billion, $24.8 billion, and $10.7 billion, respectively, based on sales generated in the 12 months following the approval of a generic drug.[37]

57. Of course, when markets function competitively, the rapid gains in revenue and market share experienced by generic companies—and the substantial savings experienced by patients and health plans—come at the expense of brand companies, who see a rapid loss of revenue and market share. As a result, for brand companies like Corcept that have only one product, unfettered competition from generic drugs can be an existential threat.

V. FACTUAL ALLEGATIONS

58. Cushing's syndrome patients stood to benefit enormously from lower prices and expanded access thanks to competition from Teva's generic Korlym. But that meant Corcept stood to lose hundreds of millions of dollars in profits when faced with generic competition from Teva. As detailed below, Corcept's response was to manipulate the patent, regulatory, and distribution systems to extend its monopoly and stifle the generic competition that Congress sought to encourage. These tactics included listing patents in the Orange Book that Corcept knew (and

[36] *See, e.g.*, Henry Grabowski et al., *Continuing Trends in U.S. Brand-Name and Generic Drug Competition*, 24 J. Medical Econ. 908 (2021), https://www.tandfonline.com/doi/full/10.1080/13696998.2021.1952795.

[37] *See* Ryan Conrad et al., *Estimating Cost Savings from New Generic Approvals in 2018, 2019, and 2020*, FDA (Aug. 2022), https://www.fda.gov/media/161540/download. "Savings" are calculated by subtracting sales revenue prior to an ANDA approval by "current" sales revenue (*i.e.*, sales revenue for the unique drug product following a generic approval). These figures account for all generic approvals in these years where sales revenue data is available.

publicly admitted) did not cover Korlym and thus were ineligible to be listed there, bringing sham patent litigation, blocking access to the key pharmacy distribution channel, and improperly influencing prescriber behavior through bribes and kickbacks. This scheme is ongoing, and has been extraordinarily effective at unlawfully impeding generic Korlym competition from Teva.

A. The FDA Approves Korlym to Treat a Subset of Endogenous Cushing's Syndrome, a Rare Disorder, Under the Orphan Drug Act.

59. Korlym is a once-daily oral pill that blocks the actions of a hormone called cortisol, to reduce the side effects caused by excess cortisol in the body. On February 17, 2012, the FDA approved Korlym for a single indication: "to control hyperglycemia [*i.e.*, high blood sugar] secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery."[38]

60. Endogenous Cushing's syndrome is a debilitating and rare disease that occurs when the body is exposed to high levels of cortisol produced by the adrenal glands for a sustained period of time. Endogenous Cushing's syndrome is most commonly caused by a hormone-secreting tumor in the adrenal or pituitary glands. In the adrenal glands, the tumor produces too much cortisol. In the pituitary gland, the tumor produces too much ACTH (adrenocorticotropic hormone), a neuroendocrine hormone that tells the adrenal glands to produce cortisol. Both types of tumors result in excess cortisol production leading to Cushing's syndrome. Korlym blocks the glucocorticoid receptor type II (GR-II) to which cortisol binds, thereby inhibiting the effects of excess cortisol in Cushing's syndrome patients.

61. Endogenous Cushing's syndrome is a rare disease affecting approximately 20,000 patients in the United States.

62. Cushing's syndrome severely impacts quality of life for those who suffer from the disease. The most common symptoms of Cushing's syndrome include weight gain in the trunk, with thin arms and legs; weight gain in the face (sometimes called moon face); a fatty lump between the

[38] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202107s000lbl.pdf.

shoulders (sometimes referred to as a buffalo hump); pink or purple stretch marks on the stomach, hips, thighs, breasts, and underarms; thin, frail skin that bruises easily; slow wound healing; acne; for women, thick, dark hair on the face and body and periods that are irregular or stop; for men, lower sex drive, reduced fertility, and erectile dysfunction. Other symptoms include extreme tiredness, muscle weakness, depression, anxiety, irritability, memory loss, sleeplessness, high blood pressure, headaches, infections, bone loss, and stunted growth.

63. Cushing's syndrome can also cause a range of serious complications, including heart attacks and strokes, blood clots, depression, memory loss, type 2 diabetes, bone loss and fractures, serious or multiple infections, loss of muscle mass and strength, and other serious complications.

64. Cushing's syndrome can be fatal if left untreated. Studies have found that some patients have a life expectancy of five years or less without treatment.

65. Cushing's syndrome is typically treated by an endocrinologist. An endocrinologist is a physician who specializes in diagnosing and treating conditions that affect the body's glandular systems, including the adrenal glands, hypothalamus, pancreas, parathyroid glands, pituitary gland, reproductive glands, and thyroid, in addition to bone and lipid metabolism. Because endogenous Cushing's syndrome is so rare, only a small subset of endocrinologists nationwide specialize in diagnosing and treating Cushing's syndrome. As of 2013, approximately 300 endocrinologists treated approximately 70% of all Cushing's syndrome patients in the United States.

66. When Korlym was approved by the FDA, it qualified for what is known as "orphan" status under the Orphan Drug Act of 1983.

67. The Orphan Drug Act was enacted to promote research and development of medicines used to treat rare diseases.[39] Orphan drug designation is available for disease treatments affecting fewer than 200,000 patients in the United States.[40] Orphan drug designation is reserved for diseases and conditions that lack adequate treatments.[41]

[39] 21 U.S.C. § 360bb.

[40] *Id.*

[41] Orphan Drug Act, Pub. L. No. 97-414, § 1(b)(2) (Jan. 4, 1983) (orphan drugs are those that treat diseases and conditions for which "adequate drugs ... have not been developed").

68. Along with the orphan designation, the developing sponsor obtains certain benefits, including tax credits for clinical testing, assistance from the FDA in the drug development process, and seven years of marketing exclusivity for the drug.[42] The market exclusivity period begins when the FDA approves the drug, but a brand drug company must comply with FDA requirements in order to maintain orphan drug exclusivity "for the full 7-year term of exclusive approval."[43]

69. The FDA granted Korlym orphan drug status on July 5, 2007. The FDA approved Corcept's NDA for Korlym on February 17, 2012. To be clear, however, Corcept did not invent Korlym's active ingredient (mifepristone), its formulation, or its use for the treatment of Cushing's syndrome, all of which had been well documented by the 1980s. Nor was Corcept required to conduct large-scale clinical trials before receiving FDA approval for Korlym, because the drug was already well known and characterized long before Corcept filed its NDA.

70. Corcept launched Korlym in 2012. Corcept's orphan drug status was set to expire on February 17, 2019, seven years after Korlym received FDA approval.

B. Korlym Is Corcept's Only Product and Is Enormously Expensive and Enormously Profitable.

71. Korlym is Corcept's only FDA-approved drug. Korlym provides Corcept with 100% of its revenue.

72. Korlym is a very expensive medication. As of September 13, 2024, the website Drugs.com estimates the monthly cost (28 tablets) for a 300 mg Korlym prescription at approximately $20,403.58, or more than $244,000 per patient, per year.[44] Notably, the FDA's approved dosing guidelines provide that Korlym's daily dosage may be increased to as much as 1200 mg per day,[45] meaning that in a single year, a patient on Korlym could pay up to $980,000 for

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[42] 21 U.S.C. § 360cc.

[43] 21 C.F.R. § 316.34(a).

[44] https://www.drugs.com/price-guide/korlym (last visited Sept. 13, 2024).

[45] https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202107s008lbl.pdf at 1.

his or her prescription at the highest recommended dose. These prices remain supracompetitive even though Corcept listed an authorized generic version of Korlym on or around May 28, 2024.

73. Relative to its price tag, Korlym is very inexpensive to produce. In its most recent 10-K, Corcept reported that its "Cost of Sales"—which includes the cost of manufacturing Korlym, among other things—was just 1.3% of Corcept's total revenue for each of the years 2023 and 2022.[46] Given that 100% of Corcept's revenue derives from sales of Korlym, it is apparent that Corcept's profit margins for Korlym are equal to 98.7% at minimum. Put another way, Corcept has been able to price Korlym at nearly 77-times the marginal cost of manufacturing it.

C. Teva Files an ANDA Seeking FDA Approval to Market a Generic Version of Korlym—But Is Blocked by Patents Corcept Improperly Listed in the Orange Book and Corcept's Sham Patent Infringement Litigation.

74. On December 15, 2017, Teva filed ANDA 211436. Teva's ANDA was the first ANDA to seek approval for a generic version of Korlym.

75. At the time Teva filed its ANDA, Corcept had only two patents for Korlym listed in the Orange Book: U.S. patent number 8,921,348 (the '348 patent) and U.S. patent number 9,829,495 (the '495 patent). Neither of these patents had a connection to the approved Korlym label. Corcept's weak intellectual property rights reflect the fact that Corcept did not undertake significant innovation in bringing Korlym to market. As noted above, Korlym's active ingredient (mifepristone), mifepristone formulations, and the use of mifepristone to treat Cushing's syndrome, were all well known decades before Corcept submitted its NDA.

76. Teva's ANDA included a Paragraph IV certification with respect to both the '348 and '495 patents. Because Teva's ANDA was the first ANDA with a Paragraph IV certification for a generic version of Korlym, Teva's ANDA was eligible for a 180-day exclusivity period upon receiving FDA approval and launching.

[46] https://ir.corcept.com/static-files/455a877a-cbe5-4bd2-8953-5f208a6d6642 at 33, 36 (reporting 2023 cost of sales were $6.5 million, compared to net product revenue of $482.4 million, and reporting 2022 cost of sales were $5.4 million, compared to net product revenue of $401.9 million).

77. Corcept sued Teva for infringing the '348 and '495 patents in the United States District Court for the District of New Jersey on March 15, 2018.[47] By filing that lawsuit, Corcept triggered a 30-month stay of FDA approval for Teva's generic. If the '348 and '495 patents had not been listed in the Orange Book at the time Teva filed its ANDA, Corcept could not have triggered a 30-month stay of FDA approval for Teva's generic, even if Corcept had sued Teva for infringement of those same patents.

78. Teva's ANDA received tentative approval on October 12, 2018—less than 10 months after Teva filed the ANDA.[48] According to the FDA's tentative approval letter, the only thing preventing Teva from receiving final approval at that time was the existence of the 30-month stay triggered by Corcept's lawsuit over the '348 and '495 patents, and the pendency of litigation with respect to those two patents.[49] Teva's ANDA received final approval when the 30-month stay expired, in August 2020.

79. Notably, the FDA's tentative approval letter did not mention Korlym's orphan drug status as a barrier to Teva receiving final approval and launching generic Korlym. On the contrary, the FDA stated expressly that the ***only*** barriers to Teva receiving final approval were the existence of the 30-month stay and the pending litigation over the '348 and '495 patents. FDA regulations provide that "[i]f a sponsor's marketing application for a drug product is determined not to be approvable because approval is barred under [the Orphan Drug Act] until the expiration of the period of exclusive marketing of another drug, *FDA will so notify the sponsor in writing*."[50] Hence, the FDA's statements in Teva's tentative approval letter—which omit any mention of Korlym's orphan

[47] *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc. et al.*, No. 1:18-cv-03632-RMB-LDW (D.N.J.).

[48] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/211436Orig1s000TAltr.pdf.

[49] *Id.* at 2. Although Corcept had obtained and listed additional patents in the Orange Book for Korlym after Teva filed its ANDA, the FDA explained that "[l]itigation, if any, with respect to these patents would not create a statutory stay of approval." *Id.* at 4 n.1.

[50] 21 C.F.R. § 316.31(c) (emphasis added).

drug status as a barrier to approval—clearly indicate that Korlym's orphan drug status in fact was ***not*** a barrier to Teva receiving approval in October 2018.[51]

80. These facts demonstrate that if Corcept had not fraudulently listed the '348 and '495 patents in the Orange Book, the Hatch-Waxman Act's 30-month stay would not have been triggered, and Teva would have received final FDA approval (instead of tentative approval) in October 2018. And Teva would have launched as early as that date, or shortly thereafter.

81. In the alternative, if the FDA had believed Korlym's orphan drug status was an obstacle to Teva receiving final approval (contrary to the FDA's statements in Teva's tentative approval letter), Teva would have received final approval as soon as Korlym's orphan drug status expired on February 17, 2019, and Teva would have launched as early as that date, or shortly thereafter. In that scenario, Teva still would have received final FDA approval almost 18 months earlier than it did in the real world, as a result of the 30-month stay triggered by Corcept's fraudulent listing of the '348 and '495 patents in the Orange Book.

82. In either scenario, Corcept successfully (and substantially) delayed Teva's FDA approval and launch as a result of its decision to fraudulently list patents it knew and publicly admitted did not cover Korlym (the '348 and '495 patents) in the Orange Book.

1. Corcept Listed the '348 and '495 Patents in the Orange Book Even Though It Knew Those Patents Did Not Cover Korlym, and Thus Were Ineligible to Be Listed.

83. Corcept did not obtain the '348 and '495 patents until years after it received FDA approval for Korlym. In fact, Corcept only obtained the '348 patent on December 30, 2014, and the '495 patent on November 28, 2017—nearly three and five-and-a-half years, respectively, after

[51] The FDA has "narrowly interpreted the [Orphan Drug Act's] exclusivity provision." Cong. Rsch. Serv., *The Orphan Drug Act: Legal Overview and Policy Considerations* at 1 (Mar. 5, 2024), https://crsreports.congress.gov/product/pdf/IF/IF12605/2. Fact and expert discovery may be necessary to understand why the FDA did not regard Korlym's orphan drug status as a barrier to granting final approval to Teva's ANDA in October 2018. But a brand company is not guaranteed to maintain its orphan drug exclusivity for the full seven-year term. For example, every brand company receives a "written notice" from the FDA to "inform the sponsor of the requirements for maintaining orphan-drug exclusive approval for the full 7–year term of exclusive approval." 21 C.F.R. § 316.34(a). On information and belief, at some point prior to October 2018, the FDA determined that Corcept failed to meet the requirements for maintaining Korlym's orphan drug exclusivity for its full seven-year term.

receiving FDA approval in February 2012. Corcept listed the '348 patent in the Orange Book on January 27, 2015, and it listed the '495 patent in the Orange Book on November 28, 2017. Corcept listed those patents in the Orange Book at the direction of Joseph Belanoff, M.D., Corcept's co-founder, President, and CEO, who is listed as the inventor of the '348 patent.

84. Corcept obtained the '348 and '495 patents and listed them in the Orange Book despite knowing that they had "no express connection" to Korlym and thus were not eligible for Orange Book listing, as explained in more detail below, and as Corcept would subsequently acknowledge on a public earnings call. Corcept listed them in the Orange Book anyway because Corcept feared losing its Korlym monopoly and wanted to forestall generic competition for as long as possible, by any means possible.

85. The '348 patent is entitled "Optimizing Mifepristone Levels in Plasma Serum of Patients Suffering from Mental Disorders Treatable with Glucocorticoid Receptor Antagonists."[52]

86. The '348 patent has one independent claim, which claims "[a] method for optimizing levels of mifepristone in a patient suffering from a disorder amenable to treatment by mifepristone, the method comprising: treating the patient with seven or more daily doses of mifepristone over a period of seven or more days; testing the serum levels of the patient to determine whether the blood levels of mifepristone are greater than 1300 ng/mL; and adjusting the daily dose of the patient to achieve mifepristone blood levels greater than 1300 ng/mL."[53]

87. The '495 patent is entitled "Method for Differentially Diagnosing ACTH-Dependent Cushing's Syndrome."[54] The '495 patent has two independent claims.

88. The first independent claim of the '495 patent claims "[a] method of concurrently treating Cushing's syndrome and differentially diagnosing adrenocorticotropic hormone (ACTH)-dependent Cushing's syndrome in a patient where the differential diagnosis is between ectopic

[52] '348 patent at 1.

[53] '348 patent col. 16 l. 25-35. The '348 patent also has six dependent claims (claims 2-7), which depend directly or indirectly from claim 1. *See id.* col. 6 l. 36-53.

[54] '495 patent at 1.

ACTH syndrome and Cushing's disease, the method comprising the steps of: (i) selecting a patient with Cushing's syndrome and also elevated ACTH levels; (ii) administering a dose of glucocorticoid receptor antagonist (GRA) sufficient to increase ACTH from the pituitary gland by at least two fold in persons with normal Hypothalamus Pituitary Adrenal (HPA) function; (iii) waiting for at least two hours; and, (iv) obtaining from the patient an ACTH concentration ratio wherein the ratio is derived from the ACTH concentrations in fluid obtained from either the left or right inferior petrosal venous sinus and from fluid obtained from a periphery venous sample; wherein an ACTH concentration ratio of greater than 3 for the ACTH concentration from the inferior venous sinus sample over the periphery venous sinus sample is diagnostic of Cushing's disease."[55]

89. The second independent claim of the '495 patent claims "[a] method of concurrently treating Cushing's syndrome and obtaining a measurement indicative of differential diagnosis of adrenocorticotropic hormone (ACTH)-dependent Cushing's syndrome in a patient where the differential diagnosis is between ectopic ACTH syndrome and Cushing's disease, the method comprising the steps of: determining the ACTH concentration ratio from a patient with Cushing's syndrome and an elevated ACTH level, where the patient has been administered a dose of glucocorticoid receptor antagonist (GRA) at least two hours prior to the removal of venous samples and where the amount of GRA administered to the patient is sufficient to increase ACTH from the pituitary gland by at least two fold in persons with normal Hypothalamus Pituitary Adrenal (HPA) function; wherein the ACTH concentration ratio is derived from the ACTH concentrations in fluid obtained from either the left or right inferior petrosal venous sinus and from fluid obtained from a periphery venous sample; and wherein an ACTH concentration ratio of greater than 3 for the ACTH concentration from the inferior venous sinus sample over the periphery venous sinus sample is indicative of Cushing's disease."[56]

[55] '495 patent col. 33 l. 2-23.

[56] '495 patent col. 36 l. 66 – col. 37 l. 21. The '495 patent also has 16 dependent claims (claims 2-17) that depend directly or indirectly from claim 1 and further limit the periphery venous sample or the glucocorticoid receptor antagonist. *See id.* col. 33 l. 24 – col. 36 l. 65.

90. Corcept knew that it was plainly improper and fraudulent for Corcept to list the '348 and '495 patents in the Orange Book for Korlym, because these patents do not actually read on the Korlym NDA or its FDA-approved labeling and, thus, do not cover Korlym in the first place.

91. As discussed above, the Hatch-Waxman Act and FDA regulations provide that a patent may ***only*** be listed in the Orange Book if it "claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or claims a method of using such drug for which approval is sought or has been granted in the application."[57]

92. The '348 and '495 patents are method-of-use patents. Neither patent even purports to claim Korlym's drug substance (active ingredient) or drug product (formulation or composition).

93. FDA regulations provide that "[f]or patents that claim a method of use, the applicant must submit information only on those patents that claim indications or other conditions of use for which approval is sought or has been granted in the NDA," and "[f]or approved NDAs, the NDA holder submitting information on the method-of-use patent must identify with specificity the section(s) and subsection(s) of the approved labeling that describes the method(s) of use claimed by the patent submitted."[58] "[T]his regulation narrows [the method-of-use] category of listable patents to those that (1) claim methods of use, wherein (2) those methods of use are directly relevant to the NDA in question."[59]

94. Once again, and as noted above, the '348 and '495 patents do not read on the Korlym NDA or its FDA-approved labeling. In turn, these patents plainly do not meet the criteria for listing method-of-use patents in the Orange Book, because neither claims the "method of using" Korlym for which approval was "sought" or "granted" in Corcept's Korlym NDA.[60]

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[57] 21 U.S.C. § 355(b)(1)(A)(viii).

[58] 21 C.F.R. § 314.53(b)(1).

[59] *Jazz Pharms.*, 60 F.4th at 1380.

[60] 21 U.S.C. § 355(b)(1)(A)(viii).

95. For example, as recited in the FDA's NDA Summary Review packet for Korlym, "Corcept Therapeutics has submitted this new drug application (NDA) ... for the use of Korlym (mifepristone) in the treatment of patients with endogenous Cushing's syndrome who have failed surgery or are not candidates for surgery.... [T]his application is ***only*** for the treatment of endogenous Cushing's syndrome."[61] Likewise, Korlym's FDA-approved label provides (and has always provided) that Korlym is indicated ***only*** "to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery."[62]

96. As such, Corcept's NDA neither sought nor obtained FDA approval for a method of using Korlym for optimizing levels of mifepristone in patients suffering from a disorder amenable to treatment by mifepristone (as claimed in the '348 patent), or for the differential diagnosis of ACTH-dependent Cushing's syndrome (as claimed in the '495 patent).

97. Furthermore, as explained above, FDA regulations require that for method-of-use patents to be listed in the Orange Book, the NDA holder must "identify with specificity the section(s) and subsection(s) of the approved labeling that describes the method(s) of use claimed by the patent."[63] But the Korlym label makes no mention of the methods of optimizing mifepristone levels that are claimed by the '348 patent, or the differential diagnostic methods that are claimed by the '495 patent.

98. The '348 and '495 patents do not read on the Korlym NDA or its FDA-approved labeling and, as a result, it was improper and fraudulent for Corcept to list the '348 and '495 patents in the Orange Book for Korlym. Corcept knew as much, because Corcept recognized the plain and

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[61] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000SumR.pdf at 1 (emphasis added).

[62] https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202107s008lbl.pdf at 1, 3 (current label); https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202107s007lbl.pdf at 1, 3 (May 2017 amended label); https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/2021-07s006lbl.pdf at 1, 3 (October 2016 amended label); https://www.accessdata.fda.gov/drugs-atfda_docs/label/2012/202107s000lbl.pdf at 1, 3 (original label).

[63] 21 C.F.R. § 314.53(b)(1); *see also Jazz*, 60 F.4th at 1380.

obvious disconnect between the '348 and '495 patents on the one hand, and the Korlym NDA and FDA-approved labeling on the other.

99. Simply put, Corcept subjectively knew that the '348 and '495 patents were ineligible for listing in the Orange Book because they do not actually cover Korlym. The only reason Corcept listed them anyway was to create grounds to trigger the Hatch-Waxman Act's 30-month stay of approval for Teva's generic product.

100. In fact, on a quarterly earnings call in February 2019, Charles Robb—Corcept's CFO—admitted that the '348 and '495 patents do not have "a direct read on the Korlym label" or any "express connection" to the Korlym label.[64] Specifically, Robb admitted that "the one quality the '214 patent [which Corcept later acquired in February 2019] has, that the other patents [including the '348 and '495 patents] do not, is a direct read on the Korlym label. And that is considered by many people be an especially powerful thing and that's really the difference. It's the first of our patents that has that express connection."[65] Robb's candid remarks were a clear admission that Corcept knew the '348 and '495 patents never should have been listed in the Orange Book, because (to quote Robb himself) they do not "read on the Korlym label," and FDA regulations have long provided that a brand company is ***only*** permitted to list a method-of-use patent in the Orange Book if it can "identify with specificity the section(s) and subsection(s) of the ***approved labeling*** that describes the method(s) of use claimed by the patent."[66]

101. As explained previously, the FDA serves only a ministerial role in maintaining the Orange Book. It accepts and publishes whatever patents a brand company submits. Corcept knowingly exploited that lack of oversight by listing patents in the Orange Book that it knew did not satisfy the requirements of federal law, for the sole purpose of triggering the Hatch-Waxman Act's 30-month stay of approval for Teva's ANDA and thereby delaying generic competition.

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[64] https://www.fool.com/earnings/call-transcripts/2019/02/26/corcept-therapeutics-incorporated-cort-q4-2018-ear.aspx.

[65] *Id.*

[66] 21 C.F.R. § 314.53(b)(1) (emphasis added); *see also Jazz*, 60 F.4th at 1380.

2. Corcept Brought Sham Patent Litigation to Delay Competition from Teva's Generic Korlym.

102. For the reasons explained above, Corcept knew—as every reasonable drug manufacturer would have known—that the '348 and '495 patents were improperly listed in the Orange Book. That circumstance alone means that the ensuing patent infringement litigation was a sham that was objectively baseless and brought in subjective bad faith for the purpose of delaying generic competition.

103. In addition, Corcept knew—as every reasonable drug manufacturer would have known—that the '348 and '495 patents were not infringed by Teva's proposed generic. As explained, neither of those patents claim the proposed drug product or FDA-approved indication for Korlym, and none of the methods claimed in those patents can be found ***anywhere*** in the Korlym label or Teva's proposed mifepristone product label. Accordingly, and just as these patents should never have been listed in the Orange Book because they do not actually cover Korlym, so too were Corcept's infringement claims objectively baseless, for precisely that same reason.

104. Moreover, Corcept brought its infringement case against Teva in subjective bad faith, for the purpose of delaying generic competition.

105. As noted above, Corcept's CFO, Charles Robb, admitted that the '348 and '495 patents do not have "a direct read on the Korlym label" or any "express connection" to the Korlym label. Robb was thus admitting that Corcept knew (as every reasonable manufacturer would have known) that neither patent covered Teva's proposed generic, making Corcept's infringement claims objectively baseless and proving that Corcept brought them in subjective bad faith.

106. Furthermore, Teva made substantial disclosures to Corcept before Corcept filed suit, which leave no room for doubt that Corcept's infringement claims were objectively baseless and brought in subjective bad faith.

107. On January 31, 2018, Teva provided Corcept with notice of Teva's Paragraph IV certification as required under the Hatch-Waxman Act, including "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."[67] In

[67] 21 U.S.C. § 355 (j)(2)(B)(iv)(II).

the detailed statement, attached as Exhibit A (the "Detailed Statement"), Teva demonstrated that its generic mifepristone ANDA did not infringe either of Corcept's '348 or '495 patents.[68]

108. First, Teva demonstrated in its Detailed Statement that its ANDA did not infringe any claim of the '348 patent. As explained above, the '348 patent's only independent claim requires, among other things, "testing the serum levels of the patient to determine whether the blood levels of mifepristone are greater than 1300 ng/mL."[69] Teva's Detailed Statement demonstrated Teva, through its ANDA, would ***not*** test the serum levels of mifepristone in patients, and thus showed that it would not directly infringe independent claim 1 of the '348 patent.[70] Teva further demonstrated that its ANDA product would not infringe the '348 patent under the doctrine of equivalents.[71] Finally, because Teva's label did not even mention, let alone encourage, testing the serum levels of patients (because Teva's proposed label was identical to Korlym's FDA-approved label, and was thus silent as to any such testing), Teva's ANDA would not induce infringement of the '348 patent.[72] And because claims 2-7 of the '348 patent all depend directly or indirectly from claim 1, Teva demonstrated that its ANDA would not infringe any claim of the '348 patent.[73]

109. Based on the Detailed Statement, there was no objective basis for Corcept to file suit asserting infringement of the '348 patent.

110. Teva's Detailed Statement also demonstrated that its ANDA did not infringe any claim of the '495 patent.[74] Teva demonstrated that its mifepristone ANDA did not directly infringe independent claim 1 of the '495 patent, either literally or under the doctrine of equivalents, because

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[68] The Detailed Statement appears as an enclosure beginning on page 10 of the PDF attached as Exhibit A.

[69] '348 patent col. 16 l. 31-33.

[70] Ex. A, Detailed Statement at 10.

[71] *Id.* at 10-11.

[72] *Id.* at 11-12.

[73] *Id.* at 13.

[74] *Id.* at 15-16.

Teva would not meet multiple limitations, including "selecting a patient," much less a patient with Cushing's syndrome or elevated ACTH, as required by claim 1 of the '495 patent.[75] Teva would also not perform the patented steps because Teva would not be diagnosing patients.[76] Similarly, Teva demonstrated that its mifepristone ANDA did not directly infringe independent claim 18 of the '495 patent, either literally or under the doctrine of equivalents, because Teva would not meet multiple limitations, including performing the step of "determining the ACTH concentration ratio," as required by claim 18 of the '495 patent.[77] And because claims 2-17 all depend directly or indirectly from claim 1, Teva demonstrated its ANDA would not directly infringe any claim of the '495 patent.[78] In addition, Teva demonstrated that its ANDA would not induce infringement of the '495 patent, because Teva's proposed label was identical to Korlym's FDA-approved label, and thus did not mention—let alone encourage—taking the steps required by any claim of the '495 patent.[79]

111. Based on the Detailed Statement, there was no objective basis for Corcept to file suit asserting infringement of the '495 patent.

112. After receiving Teva's Detailed Statement, Corcept had no good faith basis to file a lawsuit. No reasonable litigant would have filed a lawsuit against Teva for infringing the '348 and '495 patents after receiving Teva's Detailed Statement.

113. Because Teva's label made plain that Teva's ANDA would not infringe or encourage infringement of the '348 and '495 patents, Teva filed a motion to dismiss Corcept's infringement suit for failure to state a claim in June 2018.[80] The court denied Teva's motion in October 2018, holding that Corcept had satisfied the applicable pleading standards "by alleging that it is the holder

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[75] *Id.*

[76] *Id.*

[77] *Id.*

[78] *Id.* at 18.

[79] *Id.* at 17-18.

[80] *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc. et al.*, No. 1:18-cv-03632-RMB-LDW (D.N.J.), Dkt. 12.

of the patents-in-suit and that Teva has infringed or will infringe on at least one claim in each of the patents-in-suit."[81] The court refused to review Teva's proposed label as part of its analysis, explaining in a footnote that it would not be appropriate to consider Teva's proposed label in deciding the motion to dismiss and that the question of how physicians would interpret Teva's label was a "factual dispute" that could not be resolved on a motion to dismiss.[82] Although the court declined to consider Teva's proposed label on a motion to dismiss, Corcept knew of Teva's proposed label, and knew that it was identical to Korlym's FDA-approved label. And Corcept knew very well that the '348 and '495 patents did not read on the Korlym label—as Corcept would later admit—and thus also knew that the '348 and '495 patents did not read on Teva's generic product label, either. As such, the court's denial of Teva's motion to dismiss said nothing about whether Corcept's infringement claims were objectively baseless and pursued in subjective bad faith.

114. The objective baselessness and subjective bad faith of Corcept's infringement claims are confirmed by the fact that Corcept did not even serve expert opinions on infringement of the '348 and '495 patents when expert reports were due in November 2020—and a few months later, Corcept decided to drop its infringement claims on both the '348 and '495 patents altogether. In January 2021, Corcept informed Teva that it was voluntarily dismissing its infringement claims under both the '348 and '495 patents (as well as infringement claims under other, later-asserted patents).[83]

115. Between the date Corcept sued Teva under the '348 and '495 patents, and the date Corcept voluntarily dismissed its infringement claims, Corcept had not learned any material new information bearing on the strength of its claims. Corcept's voluntary dismissal was an acknowledgement that its infringement claims were always objectively baseless and were brought in

[81] *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, 2018 WL 5263278, at *3 (D.N.J. Oct. 23, 2018).

[82] *Id.* at *3 n.3

[83] *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc. et al.*, No. 1:18-cv-03632-RMB-LDW (D.N.J.), Dkt. 266.

subjective bad faith for the purpose of delaying FDA approval of Teva's generic and thwarting competition.

3. Corcept Engages in Additional Bad-Faith Litigation Tactics to Further Delay Competition from Teva's Generic Korlym.

116. After knowingly misusing the Orange Book and initiating sham infringement litigation to trigger a 30-month stay of FDA approval of Teva's generic, Corcept then engaged in a series of bad-faith litigation tactics that were designed to further prolong the litigation and delay Teva's launch.

117. For example, in February 2019, Corcept received a new patent that purportedly covered Korlym: U.S. patent number 10,195,214 (the '214 patent). This patent claimed a method of treating Cushing's syndrome in patients taking a daily 1200 mg or 900 mg dose of mifepristone, by reducing the daily dose to 600 mg and concomitantly administering a strong CYP3A inhibitor.[84] Corcept immediately sued Teva for infringing the '214 patent. It was objectively baseless and a sham for Corcept to sue Teva for infringing the '214 patent, because there was no basis to suggest that Teva's proposed label would encourage infringement of the '214 patent. The sham nature of Corcept's '214 infringement claim is confirmed by the fact that when Teva and Corcept finally went to trial in September 2023, Corcept was unable to identify a single instance of anyone ever practicing the method claimed in the '214 patent. Corcept's only reason for suing Teva under the '214 patent was to further tie up Teva in baseless, distracting infringement litigation.

118. In addition, in March 2023, Corcept sued Teva for infringing two more patents: U.S. patent number 10,842,800 (the '800 patent), and U.S. patent number 10,842,801 (the '801 patent). Corcept had acquired these patents in November 2020. Corcept thus waited nearly two-and-a-half years after acquiring the '800 and '801 patents to actually sue Teva for allegedly infringing those patents. That delay can only be explained as a bad-faith tactic to push off the trial date, especially considering that Corcept had asserted both the '800 and '801 patents two years earlier—in March

[84] '214 patent col. 68 l. 2-16.

2021—against another generic pharmaceutical company, Hikma Pharmaceuticals, which had also filed an ANDA for approval of a generic version of Korlym.[85]

119. Corcept's piecemeal litigation strategy against Teva had no legitimate purpose and was pursued in bad faith as a means of stifling competition and illicitly prolonging Corcept's monopoly by delaying resolution of the patent case and Teva's eventual launch.

120. In fact, in April 2023, Judge Bumb—who presided over Corcept's litigation against Teva—harshly criticized Corcept for its "decision to belatedly file" suit on the '800 and '801 patents, which Judge Bumb characterized as "a tactical decision to delay proceedings" that was of Corcept's "own making and at its own peril."[86] Judge Bumb expressed serious frustration at Corcept's manipulation of the court's docket, writing that "[t]his Court cannot function properly if all parties before it were permitted to litigate their claims in piecemeal fashion, as has happened here."[87]

121. In all, Corcept asserted nine different patents against Teva in ***four*** separate lawsuits Corcept filed between 2018 and 2023, strategically timing each lawsuit to maximize delay. Of the nine patents Corcept asserted, Corcept voluntarily dismissed seven of them, including (as noted above) the '348 and '495 patents that were the basis for the 30-month stay. The seven patents that Corcept asserted but then voluntarily dismissed are the '348 and '495 patents, which Corcept asserted in March 2018 and informed Teva it was voluntarily dropping in January 2021[88]; U.S. Patent No. 9,943,526 (the '526 patent), which Corcept asserted in July 2018 and informed Teva it was voluntarily dropping in July 2019[89]; U.S. Patent No. 10,166,242 (the '242 patent) and U.S.

[85] *Corcept Therapeutics, Inc. v. Hikma Pharms. USA Inc.*, No. 2:21-cv-05034-EP-LDW (D.N.J.).

[86] *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 1:18-cv-03632-RMB-LDW (D.N.J.), Dkt. 239.

[87] *Id.* Judge Bumb further noted that "[t]he Court rejects Corcept's attempt to pass the blame onto Teva because it failed to file a declaratory judgment action." *Id.*

[88] *Id.* Dkt. 1 (asserting infringement of '348 and '495 patents); *id.* Dkt. 266 (voluntarily dismissing claims under '348 and '495 patents).

[89] *Id.* Dkt. 15 (asserting infringement of '536 patent); *id.* Dkt. 129 (voluntarily dismissing claim under '526 patent).

Patent No. 10,166,243 (the '243 patent), which Corcept asserted in February 2019 and informed Teva it was voluntarily dropping in July 2019[90]; U.S. Patent No. 10,500,216 (the '216 patent), which Corcept asserted in December 2019 and informed Teva it was voluntarily dropping in August 2023[91]; and the '801 patent, which Corcept asserted in March 2023 and informed Teva it was voluntarily dropping in August 2023.[92] This strategy was part of an overall scheme, pursued in bad faith, to tie up Teva in litigation for as long as possible, to prolong Corcept's monopoly and delay generic competition for as long as possible. There was no objective or subjective basis for Corcept to allege infringement of ***any*** of the patents it asserted against Teva, because ***none*** of those patents claim the proposed drug product or FDA-approved indication for Korlym, and ***none*** of the methods claimed in ***any*** of those patents can be found ***anywhere*** in the Korlym label or Teva's proposed mifepristone product label.

122. Corcept and Teva ultimately proceeded to a bench trial in front of Judge Bumb in late September 2023, in which Corcept asserted infringement claims under just two patents: the '214 patent, and the '800 patent. On December 29, 2023, Judge Bumb ruled in Teva's favor, holding that Teva's generic did not infringe either of the last two asserted Corcept patents.[93] Between the seven patents Corcept voluntarily dismissed, and the two patents Corcept brought to trial and lost, Corcept was not successful on ***any*** infringement claim it asserted against Teva. Corcept brought these lawsuits without regard to their merits, but rather for the purpose of injuring and harassing Teva.

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[90] *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2:19-cv-05066-SDW-CLW (D.N.J.), Dkt. 1 (asserting infringement of '242 and '243 patents); *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 1:18-cv-03632-RMB-LDW (D.N.J.), Dkt. 129 (voluntarily dismissing claims under '242 and '243 patents).

[91] *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2:19-cv-21384-SDW-LDW (D.N.J.), Dkt. 1 (asserting infringement of '216 patent); *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 1:18-cv-03632-RMB-LDW (D.N.J.), Dkt. 266 (voluntarily dismissing claim under '216 patent).

[92] *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 1:23-cv-01505-RMB-LDW (D.N.J.), Dkt. 1 (asserting infringement of '801 patent); *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 1:18-cv-03632-RMB-LDW (D.N.J.), Dkt. 266 (voluntarily dismissing claim under '801 patent).

[93] *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 1:18-cv-03632-RMB-LDW (D.N.J.), Dkt. 301.

123. As Corcept intended, Corcept's bad-faith litigation tactics succeeded in delaying resolution of its infringement claims until the very end of 2023, close to six years after Corcept had originally filed suit in early 2018. That length of time is far outside the norm in Hatch-Waxman patent infringement litigation. In the District of New Jersey (where the Corcept-Teva litigation took place), in 2016 and 2017, the median time to trial in Hatch-Waxman litigation was 795 days, or just over two years.[94] The highly unusual delay, combined with all of the circumstances detailed above, underscores that Corcept brought its series of objectively baseless infringement cases against Teva in subjective bad faith, for the purpose of delaying generic competition.

D. Teva Launches Generic Korlym, But Corcept Stifles Competition by Blocking Access to the Critical Optime Distribution Channel and Paying Bribes and Kickbacks to Physicians.

124. Following its trial victory over Corcept, Teva launched generic Korlym on January 19, 2024, just three weeks after Judge Bumb's decision.

125. As explained above, when pharmaceutical markets operate competitively as Congress intended, the first generic on the market almost always rapidly takes market share and revenue from the brand company, often capturing 60-75% or more of the market within the first six months, and usually more than 80% within the first year.[95]

126. That has not happened in the market for Korlym—even though Corcept continues to charge supracompetitive prices notwithstanding competition from Teva's lower-priced generic, and did not even launch an authorized generic until the end of May 2024.

127. According to drug industry pricing compendia, which contain publicly available information about drug prices, Teva's generic launched at a 13% price discount compared to brand Korlym, and Teva offers copay assistance to commercially insured patients, potentially reducing out-

[94] Steve Brachmann, *Hatch-Waxman Litigation: 60 Percent Increase in ANDA Lawsuits from 2016 to 2017* (May 16, 2018), https://ipwatchdog.com/2018/05/16/hatch-waxman-litigation-60-percent-increase-anda-lawsuits/id=96985/.

[95] *See, e.g.*, Henry Grabowski et al., *Continuing Trends in U.S. Brand-Name and Generic Drug Competition*, 24 J. Medical Econ. 908 (2021), https://www.tandfonline.com/doi/full/10.1080/13696998.2021.1952795.

of-pocket costs to $0 for those consumers.[96] Teva's pricing is close to the average discount for a first generic compared to the brand price.[97] A 13% discount alone would translate into savings of approximately $30,000 per patient, per year, at the lowest recommended dose (300 mg per day), and savings of approximately $120,000 per patient, per year, at the highest allowed dose (1200 mg per day).

128. To this day, the price of Teva's generic Korlym is materially below the price of Corcept's brand Korlym.

129. Despite being the first and only generic on the market for nearly twenty four months, and being priced at a material discount to brand Korlym, Teva has not captured the expected 60-75% of the market that one nearly always sees. Instead, ***Teva's market share has been close to zero***, currently standing at less than 4% of the Korlym market.

130. In fact, on Corcept's quarterly earnings call on May 1, 2024, Sean Maduck—Corcept's President of Endocrinology—boasted that "we are not aware of losing any patients to generic mifepristone. And based on our analysis at this point, we believe generic Korlym has been available to some degree for a couple of months, but it hasn't had any impact on our business."[98] Furthermore, on the same earnings call, Corcept announced that it was revising its projected earnings ***upward***, and was now projecting annual revenue of $620 – $650 million for 2024, despite the fact that all of Corcept's revenue comes from sales of Korlym.[99] Maduck declared that Corcept was

[96] The Capitol Forum, *Health Care Antitrust Weekly* at 5 (Jan. 24, 2024), https://csro.info/UserFiles/file/Articles/HealthCareAntitrustWeekly2024-01-24HealthCareAntitrustWeeklyKlobuch-arPressesDrugmakers.pdf.

[97] As noted above, some studies show that first generics launch at an 18% price discount compared to the brand, on average. Ass'n for Accessible Medicines, *Access Denied: Why New Generics Are Not Reaching America's Seniors* at 7 (Sept. 2019), https://accessiblemeds.org/sites/default/files/2019-09/AAM-White-Paper-Access-Denied-First-Generics-web_0.pdf.

[98] https://seekingalpha.com/article/4688346-corcept-therapeutics-incorporated-cort-q1-2024-earnings-call-transcript.

[99] *Id.*

"confident in our ability to both continue to grow our business today, but also defend our market share," notwithstanding the entry of Teva's lower-cost generic.[100]

131. Similarly, on Corcept's quarterly earnings call on July 29, 2024, Maduck reported that "[t]he Teva product has been available in the channel for many months, so it's out there, but it has had very little impact on our business."[101] Corcept announced that it was revising its projected earnings upward ***again***, and was now projecting annual revenue of $640 – $670 million for 2024, again despite the fact that all of Corcept's revenue comes from sales of Korlym.[102] And on its most recent earnings call on November 4, 2025, Corcept announced that it was projecting annual revenue of $800 – $850 million for 2025, and confirmed that it has "not seen" and does not "expect" to see "any downward pressure on margins" from generic competition "that might require modeling adjustments going forward."[103]

132. On information and belief, Corcept has not meaningfully adjusted its price to compete with Teva's generic product. To the contrary, Corcept reported revenues for 2023 of $482 million.[104] Corcept's substantially higher projections for 2024 and 2025 therefore show that Corcept's strategy of locking up distribution through its long-term exclusive dealing contract with Optime is allowing Corcept to maintain nearly 100% market share ***and*** maintain or increase prices ***despite*** the entry of a lower-priced AB-rated generic substitute.

133. These results would be impossible to explain in a competitive market. They represent a dramatic departure from the pattern of rapid generic penetration, loss of brand company revenue, and overall price declines that reliably occur in competitive pharmaceutical markets after generic entry.

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[100] *Id.*

[101] https://seekingalpha.com/article/4707818-corcept-therapeutics-incorporated-cort-q2-2024-earnings-call-transcript.

[102] *Id.*

[103] https://www.fool.com/earnings/call-transcripts/2025/11/27/corcept-cort-q3-2025-earnings-call-transcript/.

[104] https://ir.corcept.com/static-files/455a877a-cbe5-4bd2-8953-5f208a6d6642 at 33.

134. But Corcept's CEO, Joseph Belanoff, told investors that Corcept had been "thinking about" the possibility of generic competition "for a long time and we've been prepared for this possibility since 2020. We have a plan in place and we will continue to revise that plan as we receive new market intelligence and as I said before, we're continuing to invest in our Korlym business and we're confident in our ability to both grow and protect the share that we have."[105]

135. It is now apparent that Corcept's "plan" was to thwart generic competition by locking up the most effective distribution channel for Korlym through a highly unusual, anticompetitive exclusive-dealing agreement with a key pharmacy, as well as paying bribes and kickbacks to physicians as compensation for continuing to prescribe brand Korlym.

1. Corcept Entrenches Its Monopoly Through an Anticompetitive Exclusive-Dealing Agreement.

136. A central reason Teva's lower-cost generic Korlym has failed to gain more than a toehold in the market is because Corcept has locked up the key distribution channel by entering a long-term, unprecedented, blanket exclusive-dealing arrangement with the only pharmacy that distributed brand Korlym from 2017 until very recently.

137. From 2017 until very recently, Corcept distributed Korlym exclusively through the specialty pharmacy Optime. Under the Corcept-Optime distribution agreement, Optime is forbidden to distribute any products that compete with Korlym—including generic versions of Korlym. As disclosed in Corcept's SEC filings, the agreement provides in express terms that "Optime shall not, directly or indirectly, perform services for any third party with respect to a treatment or potential treatment (whether generic or otherwise) for any disorder treated by a Product [*i.e.*, Korlym], unless otherwise specifically agreed to by the Parties."[106]

[105] https://seekingalpha.com/article/4670850-corcept-therapeutics-incorporated-cort-q4-2023-earnings-call-transcript.

[106] https://ir.corcept.com/static-files/a461c17e-29e7-4bdf-9b86-b745fac82166 at 57, § 12.2.

138. According to Corcept's SEC filings, Corcept's agreement with Optime has been in place since August 4, 2017, was renewed effective April 1, 2024, and has a current term that runs until March 31, 2027, with automatic renewal for successive three-year terms after that.[107]

139. The Corcept-Optime agreement has been amended three times since 2017: first on August 1, 2022, then on September 16, 2022, and finally on April 1, 2024.[108] Unredacted copies of the agreements and amendments are not publicly available, which makes it impossible to fully assess how the agreement's terms have changed over time. But Corcept's SEC filings indicate that Corcept and Optime have made numerous adjustments to the terms of their relationship, including revising the fees, services, and other obligations that Corcept and Optime owe each other in connection with the distribution of Korlym.[109] The April 1, 2024 amendment comprehensively "amend[ed] and restate[d] the 2017 Distribution Services Agreement in its entirety."[110]

140. Representatives from Teva met with representatives from Optime on May 1, 2024. Teva's objective was to persuade Optime to distribute Teva's generic Korlym product immediately—or at least to explain what Teva would need to do to persuade Optime to distribute Teva's generic Korlym product in the future. Optime's representatives made clear that there was nothing Teva could do to gain access to the Optime distribution channel. Optime's employees described the agreement with Corcept as an "evergreen" contract that effectively has no expiration date and that Optime is not free to terminate. During this meeting, Optime representatives would not even entertain a bid from Teva, even though Optime could potentially make more money by distributing Teva's generic. Citing the exclusivity provisions of its agreement with Corcept, Optime explained that it was not allowed to distribute Teva's product, no matter what terms Teva might propose.

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[107] *Id.* at 14; *id.* at 60, § 14.

[108] *Id.* at 44.

[109] *See* https://www.sec.gov/Archives/edgar/data/1088856/000162828022028203/cort93022-ex103.htm (Aug. 1, 2022 amendment); https://www.sec.gov/Archives/edgar/data/1088856/000-162828022028203/cort93022ex104.htm (Sept. 16, 2022 amendment).

[110] https://ir.corcept.com/static-files/a461c17e-29e7-4bdf-9b86-b745fac82166 at 44.

141. Unredacted copies of the Corcept-Optime agreement are not publicly available. But Corcept's SEC filings indicate that the agreement is severely one-sided in favor of Corcept.

142. For example, Corcept has the right to terminate the distribution agreement for convenience at any time, but Optime does not; Optime's only termination right is if Corcept commits a material breach that Corcept fails to cure in a reasonable time after receiving written notice.[111] As a result—and consistent with the representations made by Optime employees during their meeting with Teva—Optime is not free to cancel its agreement with Corcept, no matter how attractive an offer Teva might make it.

143. Statements that Optime employees made to Teva during their May 1, 2024 meeting likewise indicate that Optime does not consider itself free to allow the agreement to expire at the end of its current term, in 2027; rather, the agreement will remain in effect for as long as Corcept wants it to be in effect.

144. Similarly, although Optime is bound by a blanket contractual exclusivity provision that expressly forbids it from distributing products that compete with Korlym, Corcept does not appear to be bound by any similar provision restricting it from distributing Korlym through other pharmacies—and the April 1, 2024 amendments appear to have expanded Corcept's right to relieve itself of its obligation to distribute Korlym exclusively through Optime (while leaving in place Optime's express, blanket obligation not to distribute products that compete with Korlym).[112]

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[111] *Id.* at 25-26; *id.* at 60-61, § 15.

[112] As amended on April 1, 2024, Section 18.5 of the agreement provides that, with respect to individual task orders, "Optime shall be Corcept's exclusive provider of direct-to-patient pharmacy services"—but even then, Corcept can override that provision by "stat[ing] otherwise in the applicable Task Order," and Corcept can also "elect, in its sole discretion, to modify this Section 18.5 to render this Agreement non-exclusive for any given Product." *Id.* at 63, § 18.5. Optime has no similar right to modify its obligation to exclude all products that compete with Korlym. By contrast, the first three versions of the agreement do not appear to have given Corcept the broad right "to render this Agreement non-exclusive for any given Product." *See* https://www.sec.gov/Archives/edgar/data/1088856/000156459017021314/cort-ex101_392.htm § 19 (exclusivity provision of original version of agreement); https://www.sec.gov/Archives/edgar/data/1088856/000162828022028203/cort93022-ex103.htm (Aug. 1, 2022 amendment); https://www.sec.gov/Archives/edgar/data/1088856/000-162828022028203/cort93022ex104.htm (Sept. 16, 2022 amendment).

145. The agreement is not incentive-based. Rather, Optime must comply with a long-term, blanket, express prohibition on distributing rival products without exception, regardless of whether adhering to the exclusivity provision is in Optime's best financial interests, and regardless of whether Teva or any other generic company offers lower pricing or other incentives that Corcept refuses to match. As Optime employees made clear to Teva during their recent meeting, Optime has no choice but to work exclusively with Corcept even though it could potentially make more money distributing Teva's generic.

146. It is not surprising that Corcept would be able to coerce such one-sided terms in its agreement with Optime. As alleged in the federal securities class action, Optime was founded in 2015, and for many years, Corcept was its only supplier, and Korlym was the only drug it distributed. Those circumstances made Optime entirely dependent on Corcept; Optime could not risk losing its only supplier, and so felt obligated to accede to whatever terms Corcept demanded.

147. On information and belief, Optime remains heavily dependent on its relationship with Corcept for the survival of its business, and remains under intense pressure to accede to contractual terms demanded by Corcept. Statements from Optime employees to Teva made clear Optime's belief that if it were to distribute Teva's generic mifepristone product, Corcept would stop supplying it with brand Korlym and would likely never do business with it again. Such retaliation would be very damaging to Optime.

148. The Corcept-Optime agreement is highly unusual in the pharmaceutical industry. Teva does not have—and is not aware of other manufacturers having—any such agreements with pharmacies that include this sort of one-sided, blanket, perpetual exclusivity that expressly forbids the pharmacy from distributing competitor products. Based on numerous conversations with Teva employees and third parties, all of whom have extensive experience in the pharmaceutical sector, the Corcept-Optime agreement is an extreme outlier, and possibly unprecedented.

149. The Corcept-Optime exclusive agreement has had a near-total foreclosure effect on the market for Korlym. As noted above, Teva has gained miniscule market share in the twenty four months it has been on the market as the only cheaper alternative to brand Korlym, and Corcept itself

has boasted that it is "not aware of losing any patients to generic mifepristone"[113] and that Teva's generic "has had very little impact on our business" despite being nominally "in the channel for many months."[114] Because Corcept has nearly a 100% share of the market for Korlym, and because Corcept until recently sold 100% of its Korlym product through Optime, and because experience has proven that alternative distribution channels are not realistically able to threaten Corcept's dominant market share, the exclusivity provision that forbids Optime from distributing Teva's product has a nearly 100% foreclosure effect in the relevant market.

150. This exclusive-dealing arrangement has been particularly effective at foreclosing competition because Corcept spent years heavily promoting Korlym to prescribers and building a distribution system that automatically routes Korlym prescriptions to Optime. Because Korlym treats a small patient base with a limited number of physicians, Corcept has been highly successful at closely tracking prescribers and entrenching their use of the Optime distribution channel.

151. Starting in 2017—when Corcept began working with Optime—physicians had no choice but to route Korlym prescriptions through Optime, because brand Korlym faced no competitors and Optime was the only pharmacy that distributed it. Corcept took advantage of these years alone on the market to build a durable, "sticky" Optime distribution channel by developing close relationships with physicians and incentivizing them—including through illicit bribes and kickbacks, as described below—to form entrenched prescribing and referral patterns, the most important being their overwhelming, robust reliance on the Optime distribution channel.

152. On information and belief, Corcept and Optime have deployed numerous tactics, including providing certain services to physicians, to entice these same physicians to route their Korlym prescriptions through Optime. These practices—even if not anticompetitive standing alone—have (together with illicit practices like paying bribes and kickbacks to prescribers) cemented Optime as the dominant pharmacy, and entrenched the Optime distribution channel as the

[113] https://seekingalpha.com/article/4688346-corcept-therapeutics-incorporated-cort-q1-2024-earnings-call-transcript.

[114] https://seekingalpha.com/article/4707818-corcept-therapeutics-incorporated-cort-q2-2024-earnings-call-transcript.

most efficient, effective, profit-maximizing means of reaching end-consumers of Korlym. And it is precisely for this reason—*i.e.*, that access to the Optime distribution channel is a prerequisite to effectively compete in this market—that by denying Teva that very access, Corcept and Optime's highly unusual, one-sided, blanket, perpetual, express exclusivity agreement is an effective bulwark against price competition and an unreasonable and exclusionary practice that has foreclosed Teva from competing effectively and allowed Corcept to continue charging supracompetitive prices.

153. These circumstances make clear that, as a result of Corcept's "first mover" advantage (*i.e.*, the decade-plus it spent alone on the market, including several years beyond the exclusivity period it lawfully should have enjoyed), doctors at minimum face high switching costs and are resistant to switching to alternative pharmacies. Discovery will allow Teva to uncover more details about how the Optime distribution channel functions, but on information and belief, these dynamics help explain why physicians continue to route their prescriptions through Optime, even setting aside the evidence of illicit bribes and kickbacks discussed below.

154. Corcept spent years without competition (years beyond what Corcept lawfully should have enjoyed), and used that time alone on the market to spend millions of dollars cultivating relationships with physicians, incentivizing them to rely on the Optime distribution channel. Having developed entrenched physician prescribing behavior and a sticky distribution channel subject to high switching costs, Corcept is now in a position to thwart generic competition by blocking its rivals' access to that distribution channel—blocking the most efficient, effective, and profit-maximizing means of market entry—which is exactly what the exclusive-dealing agreement with Optime accomplishes, by prohibiting the dominant pharmacy from distributing generic competitors.

155. In short, Corcept first made access to the Optime distribution channel a prerequisite to effectively compete for patients in this market, and then used its exclusivity with Optime to lock up the market by depriving competitors (including Teva) of access to that same channel.

156. These results are especially pernicious and anticompetitive because the Corcept-Optime agreement operates as an end-run around state generic substitution laws and the robust price competition they are meant to promote. As described above, state substitution laws are designed to

promote rapid switching from brand drugs to generic drugs upon generic entry, to save health plans and patients money. But substitution laws cannot function if a prescription is routed to a pharmacy that does not stock the generic. And, as discussed above, Corcept continues to charge supracompetitive prices notwithstanding the launch of Teva's generic, so health plans and patients who must purchase or reimburse the product dispensed by Optime remain locked into monopoly brand pricing. The Corcept-Optime agreement therefore has the anticompetitive effect of frustrating the operation of state substitution laws and depriving Teva of a prescription base for its generic version of Korlym, while preventing the price competition that generic substitution is meant to promote.

157. Corcept has boasted about its success in circumventing state substitution laws. For example, on an earnings call in February 2024, Sean Maduck—Corcept's President of Endocrinology—answered a question about "barriers to generic adoption" and the Optime distribution channel by explaining that Corcept had put in place a "tightly controlled model" that ensures that "this is not your typical pharmaceutical market" and "automatic substitution does not happen ... like you see in a lot of these cases."[115]

158. Teva's experience has confirmed the pernicious effects of the "barriers to generic adoption" that Corcept has put in place. Indeed, Teva has faced significant hurdles—with very little success—in trying to employ existing or potential alternative channels of distribution to reach the ultimate consumers of Korlym, and has found no viable, practical, or feasible alternative distribution channels that can be used to meaningfully threaten Corcept's monopoly.

159. Teva has expended significant efforts over many months trying to make inroads on Corcept's market share by working through other channels. For example, Teva's product is available and stocked at all major national wholesalers and a specialty wholesaler. In addition, Teva has made and continues to make the product available to all major national specialty pharmacies, several regional specialty pharmacies, and several other national retail pharmacies, either directly or

[115] https://seekingalpha.com/article/4670850-corcept-therapeutics-incorporated-cort-q4-2023-earnings-call-transcript.

through wholesalers or distributors. Teva has also secured pricing on government contracts. And as explained above, Teva has maintained a material price discount compared to Korlym's price continuously from the time Teva launched. These efforts to compete outside of the Optime distribution channel have been substantial and ongoing—but they have also been ineffective, as proven by Teva's virtually nonexistent market share notwithstanding Teva's lower prices, and as gleefully confirmed by Corcept on its earnings calls.

160. Teva's inability to threaten Corcept's monopoly through alternative distribution channels underscores the high barriers to entry in the downstream Korlym market. The years that Corcept spent cementing entrenched prescriber reliance on the Optime distribution channel (including through illicit means like paying bribes and kickbacks) has—just as Corcept intended—effectively erected very high entry barriers to alternative pharmacies, making it nearly impossible for any such pharmacies to establish themselves as effective rival distribution channels.

161. In addition, Teva has attempted to gain market share by persuading Pharmacy Benefit Managers ("PBMs") and health insurers to revise their formularies to encourage a switch from brand Korlym to Teva's generic. These efforts are ongoing, but to date have also been ineffective at allowing Teva to compete, and have not enabled Teva to pose any meaningful threat to Corcept's monopoly, even though Teva's prices are lower.

162. Teva is thus reliant on access to Optime to compete, but Corcept's exclusive agreement with Optime has cut Teva off from the key pharmacy pipeline that is necessary to permit Teva to compete effectively. The economic reality is that the market for Korlym is highly concentrated, with a relatively small number of physicians and sticky, durable patterns of prescribing behavior and high switching costs. Corcept was the only company on the market for more than a decade (a position it obtained through unlawful tactics), and it used that time to entrench Optime as the only specialty pharmacy prescribers rely on when writing prescriptions. Even if Corcept had used entirely legitimate means to convince physicians to rely exclusively on Optime—which Teva disputes, given substantial evidence of bribes and kickbacks discussed below—that would not detract from the harm to competition and patients that the exclusive arrangement is causing, because

it would not change the economic reality that Teva has been unable to compete effectively without access to Optime, and that patients and health plans are paying higher prices as a result.

163. Comments by Corcept on a recent earnings call only underscore the anticompetitive effects of the Optime exclusive-dealing arrangement. In May 2024, Sean Maduck, Corcept's President of Endocrinology, claimed that "when Korlym is prescribed both the physician and the patient receive a high level of support both at intake and ongoing from both the pharmacy and Corcept. And this is support that is tremendously valued by doctors and by patients. And for this reason, physicians who prescribe Korlym have a very strong brand preference."[116]

164. Even if that explanation were true, it would be no justification for Corcept's exclusive arrangement with Optime. On the contrary, Corcept's comments confirm Corcept's understanding that rivals like Teva cannot compete effectively if they are forced to sell through alternative distribution channels.

165. Furthermore, Corcept's vague claims about the importance of "support" from Corcept and Optime are almost certainly pretextual. Korlym is a once-a-day pill that is easy to take, is not subject to a Risk Evaluation and Mitigation Strategy ("REMS") program, and does not require meaningful support from specialized pharmacists.[117]

166. In any event, even if discovery were to show that Optime offers some services or conveniences that doctors value, that would again only highlight why it is unreasonably anticompetitive and exclusionary for Corcept to block Teva from using the Optime distribution channel, because it would explain why blocking Teva's access to the preferred distribution channel

[116] https://seekingalpha.com/article/4688346-corcept-therapeutics-incorporated-cort-q1-2024-earnings-call-transcript.

[117] A REMS program is a drug safety program that the FDA can require for certain medications that have serious safety concerns. REMS programs can require physicians and pharmacists to help prevent, monitor, or manage serious safety risks by informing, educating, or reinforcing actions among patients to reduce the frequency or severity of adverse events. Drugs subject to REMS programs can therefore require frequent, ongoing services by doctors and pharmacists. Korlym is not subject to a REMS program. *See, e.g.*, Claudia Manzo, *Risk Evaluation and Mitigation Strategies (REMS)*, FDA (May 2023), https://www.fda.gov/drugs/our-perspective/risk-evaluation-and-mitigation-strategies-rems#:~:text=Risk%20evaluation%20and%20mitigation%20strategy,particular%20adverse%20event(s).

is so effective at foreclosing competition and preserving Corcept's monopoly power. Moreover, there are no procompetitive efficiencies generated by a blanket contractual provision that expressly forbids Optime from distributing rival Korlym products. Corcept could pay Optime to provide services to patients who receive brand Korlym, without forbidding Optime from distributing generic competitors—and patients who truly valued those services could simply pay a premium to stick with the brand and continue receiving whatever services Corcept and Optime provide. That Corcept has chosen *not* to compete on the merits in this fashion shows that the "services" Corcept touts are pretextual, and that Defendants' unprecedented exclusive-dealing agreement serves no legitimate end, but serves only to prolong Corcept's monopoly and supracompetitive prices by robbing patients and health plans of the opportunity to obtain Teva's lower-priced generic.

167. Corcept has exploited its entrenched monopoly position by charging higher prices than Teva, and higher prices than Corcept would be able to charge if Corcept faced genuine competition. Teva, as well as purchasers of brand and generic mifepristone—including health plans and patients—are worse off as a result.

2. Corcept Further Entrenches Its Monopoly by Paying Bribes and Kickbacks to Physicians as Compensation for Prescribing Brand Korlym.

168. To solidify physicians' use of brand Korlym and to reinforce an illicit bulwark against generic competition, Corcept has also engaged in a years-long campaign to steer prescribers, patients, and payers away from Teva's generic—specifically, by bribing physicians and other practitioners to prescribe brand Korlym by making unlawful payments as compensation for prescriptions. These allegations are supported by publicly available payment and prescription data, well-sourced allegations in a federal securities lawsuit against Corcept, reporting by investigative journalists, and an ongoing investigation into Corcept by the United States Attorney's Office for the District of New Jersey.

169. Around the time Teva filed its ANDA, Corcept began drastically increasing the amount of money it paid to physicians and non-physician practitioners who prescribed Korlym. Data available in the Centers for Medicare and Medicaid Services Open Payments database show that in 2016, Corcept paid $380,149.69 to physicians for activities not associated with research

studies. In 2018, after Teva filed its ANDA, that figure nearly tripled, to $1,023,141.04. In 2022, Corcept made $1,547,712.50 in non-research payments to physicians and non-physician practitioners. In 2023—the last year of publicly available data—Corcept made $1,213,953.55 in non-research payments to physicians and non-physician practitioners. On information and belief, Corcept's payments have grown even higher in 2024.

170. Substantial evidence indicates that a material portion of Corcept's payments have been used to illicitly compensate physicians for prescribing brand Korlym. One court in this District has already credited allegations to that effect based on eyewitness accounts of several confidential witnesses.[118]

171. These allegations are also substantiated by publicly available data, reports by investigative journalists, and an ongoing investigation by the United States Attorney's Office for the District of New Jersey—on top of the already suspicious behavior of physicians continuing to route all of their Korlym prescriptions to Optime without apparent justification.

172. As an initial matter, physician prescribing activity can be tracked in part by consulting publicly available Medicare Part D claims data.[119] This data discloses how many claims each prescriber submitted to Medicare Part D, for each drug, in each year between 2013 and 2022. Of course, Medicare Part D claims data only discloses a subset of the number of prescriptions written by a prescriber for any given drug, because Medicare Part D data does not include prescriptions paid for by means other than Medicare Part D, such as private insurance, other government benefits plans, or by patients out of pocket. Nor does Medicare Part D data disclose relationships among physicians—like which physicians are part of the same practice—as one would need to know to determine how many prescriptions are written by physicians who are affiliated with one another. Nevertheless, Medicare Part D claims data can help identify some of the physicians who were high prescribers of Korlym through 2022.

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[118] *Ferraro Fam. Found., Inc. v. Corcept Therapeutics Inc.*, 2021 WL 3748325, at *15 (N.D. Cal. Aug. 24, 2021).

[119] https://data.cms.gov/provider-summary-by-type-of-service/medicare-part-d-prescribers/medicare-part-d-prescribers-by-provider-and-drug/data.

173. In addition, publicly available "Open Payments" data from the Centers for Medicare and Medicaid Services ("CMS") discloses how much money pharmaceutical companies paid to individual physicians and non-physician practitioners in each year between 2013 and 2023.[120] Of course, CMS Open Payments data is incomplete because it does not identify relationships among physicians—like which physicians are part of the same practice—as one would need to know to determine how much money Corcept paid to physicians who are affiliated with one another. Nor does CMS Open Payments data necessarily reveal the true purpose of the payments made by pharmaceutical companies. And it also does not reveal payments made by entities affiliated with pharmaceutical companies—for example, payments made by pharmacies like Optime—which means it is likely underinclusive. Nevertheless, CMS Open Payments data can be used to identify some of the doctors who received large payments from Corcept through the end of 2023.

174. Discovery from Corcept will fill out the details on which doctors have prescribed Korlym over the years, how much Corcept and any of its affiliates have paid them during that time, and whether the payments had any legitimate purpose. But based on a review of Medicare Part D claims data and CMS Open Payments data—combined with allegations from well-placed confidential witnesses, reporting by investigative journalists, and an ongoing federal investigation—there is substantial evidence to indicate that Corcept has engaged in a years-long campaign to funnel illicit kickbacks to physicians as compensation for prescribing brand Korlym, and that this bribery campaign is ongoing.

175. For example, Dr. Jerry Back is a physician practicing in North Charleston, South Carolina. According to Medicare Part D claims data, Dr. Back submitted 115 Medicare Part D claims for Korlym in 2017, and 98 claims in 2018. Dr. Back's Medicare claims were the highest of any physician submitting Korlym claims to Medicare Part D in 2017, and were the second highest in 2018. By comparison, Dr. Back submitted only 19 Korlym claims to Medicare Part D in 2016, and he submitted zero Korlym claims in 2014 and 2015. As soon as Dr. Back began writing a substantial

[120] Payment data from 2017 to 2023 is available here: https://openpaymentsdata.cms.gov/. Payment data from 2013 to 2016 is archived here: https://www.cms.gov/priorities/key-initiatives/open-payments/data/archived-datasets.

number of Korlym prescriptions, he simultaneously became one of the largest recipients of payments from Corcept. Dr. Back's payments from Corcept skyrocketed from just $154.38 in 2016, to $55,454.60 in 2017, and $31,099.16 in 2018.

176. Dr. Back was a prime candidate to receive bribes from Corcept, as his willingness to accept illegal kickbacks from pharmaceutical companies is a matter of public record. In May 2019, Dr. Back agreed to pay the federal government $92,506.30 to settle criminal charges that he accepted illegal kickback payments from pharmaceutical company OK Compounding, L.L.C., in exchange for writing prescriptions for certain pain creams. As reported by the United States Attorney's Office for the Northern District of Oklahoma, "[b]eginning in 2013, Dr. Back prescribed ... pain creams for his patients, facilitating the sale and distribution of the creams. As compensation for his services, OK Compounding paid Dr. Back what was characterized by the parties as 'medical director fees' based upon an hourly rate. However, the payments Dr. Back received from the company were, in actuality, 'kickbacks.'"[121]

177. As the case of Dr. Back illustrates, a pharmaceutical company's stated reason for paying a physician may turn out to be a pretext masking illicit bribes. The case of Dr. Back also illustrates the limited ability of the CMS Open Payments database to expose illicit bribery and kickback schemes (and hence the need for discovery), because OK Compounding—the entity that paid Dr. Back to prescribe pain creams—does not appear as a company making payments in the CMS Open Payments database.

178. Dr. Back's payments from Corcept fit the same pattern as his kickbacks from OK Compounding, and were very likely illegal compensation for prescribing Korlym. After Dr. Back settled the federal government's kickback charges in 2019, his payments from Corcept dropped substantially (but were still noticeably high). Corcept paid Dr. Back $15,841.30 in 2019, $7,229.27 in 2020, $13,259.13 in 2021, and $7,544.55 in 2022, the last year he received payments from

[121] https://www.justice.gov/usao-ndok/pr/south-carolina-doctor-will-pay-9250630-allegedly-engaging-illegal-kickback-scheme.

Corcept. In total, between 2017 and 2022, Dr. Back received $130,582.39 in payments from Corcept, none of which were for research-related activities.

179. Similarly, Dr. Joseph Mathews is a physician practicing in Summerville, South Carolina. Like Dr. Back, Dr. Mathews dramatically increased his number of Korlym claims submitted to Medicare Part D, from just 16 Korlym claims in 2016 (and zero in 2014 and 2015), to 85 claims in 2017, 89 claims in 2018, 70 claims in 2019, 61 claims in 2020, 79 claims in 2021, and 90 claims in 2022. During that time, Dr. Mathews's payments from Corcept also skyrocketed. After receiving just $3,497.58 in 2016, Dr. Mathews received $73,777.19 in 2017, and a total of $174,328.21 between 2017 and 2022. None of those payments were for research-related activities.

180. Investigative journalists have uncovered substantial evidence of illegal payments paid by Corcept to additional physicians. For example, according to a report published in 2019 by the Foundation for Financial Journalism, drawing on an investigation by the Southern Investigative Reporting Foundation, Dr. Hanford Yau and his Veterans Administration clinic in Orlando, Florida, prescribed Korlym to 84 people from early 2016 to Sept. 1, 2018, generating at least 9% of Corcept's total revenue in 2017.[122] Simultaneously, Dr. Yau became Corcept's leading recipient of speakers bureau payments, personally receiving $95,139.66 from Corcept in 2017 alone. From 2017 to 2023—the last year for which CMS Open Payments data is available—Dr. Yau received a total of $443,531.01 in payments from Corcept, none of which was for research-related activities.

181. The case of Dr. Yau illustrates the limited ability of Medicare Part D claims data to expose illicit bribery and kickback schemes (and hence the need for discovery), because Dr. Yau has not submitted any Medicare Part D claims for Korlym, which would make it impossible to identify him as a high prescriber by relying on Medicare Part D claims data alone.

182. Other highly suspicious examples are not hard to find. For instance, Dr. Kevin M. Pantalone is a physician practicing in Cleveland, Ohio. Dr. Pantalone submitted just 12 Korlym

[122] Roddy Boyd, *Corcept Therapeutics: The Company That Perfectly Explains the Health Care Crisis*, The Foundation for Financial Journalism (Jan. 25, 2019), https://ffj-online.org/2019/01/25/corcept-therapeutics-the-company-that-perfectly-explains-the-health-care-crisis/.

claims to Medicare Part D between 2016 and 2020, and received only $2,151.55 from Corcept during that entire time. Between 2021 and 2022, however, Dr. Pantalone submitted 74 Korlym claims to Medicare Part D, and received $197,092.27 in payments from Corcept. None of Dr. Pantalone's payments were for research-related activities. In 2023, Dr. Pantalone received another $62,205.53 in payments from Corcept, none of which were for research-related activities.

183. Similarly, Dr. Matthew C. Young is a physician practicing in Colorado Springs, Colorado. Between 2016 and 2019, Dr. Young submitted just 25 Korlym claims to Medicare Part D, and received only $223.98 in payments from Corcept. Between 2020 and 2022, however, Dr. Young submitted 103 Korlym claims to Medicare Part D, and received $164,309.78 from Corcept. None of Dr. Young's payments were for research-related activities. In 2023, Dr. Young received another $62,903.15 in payments from Corcept, none of which were for research-related activities.

184. Robin M. Anderson is a Nurse Practitioner in Portage, Indiana. Anderson submitted 55 Korlym claims to Medicare Part D in 2019, 46 claims in 2020, 48 claims in 2021, and 25 claims in 2022. Corcept paid Anderson $20,503.42 in 2021, the first year pharmaceutical companies were required to report payments made to nurse practitioners to the CMS Open Payments database. In 2022, Corcept paid Anderson another $43,525.55. In 2023, Corcept paid Anderson a whopping $106,233.24. None of Anderson's payments were for research-related activities.

185. Overall, between 2017 and 2023, Corcept's top 10 payment recipients each received between $187,441.86 and $443,531.01 individually, for an average of $250,588.89 per recipient. None of those payments were for research-related activities, and in each case, Corcept paid the vast majority of those amounts ***after*** Teva had filed its ANDA. Those payments are astronomical and far outside the norm. Seven of these recipients are physicians for whom the average doctor in their specialty received $67,647 in ***total payments*** from ***all pharmaceutical companies combined*** during those years, meaning ***Corcept alone*** paid these physicians, on average, almost ***four times*** as much as all other pharmaceutical companies combined paid to comparable physicians during the same time period. Getting more extreme, one recipient is a physician for whom the average doctor in his specialty received just $5,997 in total payments from all pharmaceutical companies combined

between 2017 and 2023. But Corcept paid him $227,212.93—***more than 37 times*** as much as similar physicians received from all other pharmaceutical companies combined during those years. Even more extreme, the remaining two of Corcept's top 10 payment recipients are non-physician practitioners whom Corcept paid $217,907.04, and $187,441.86, respectively, over just three years (2021-2023), when the average practitioners in their specialties received a mere $2,719 and $1,603, respectively, from all pharmaceutical companies combined during those years. In other words, Corcept paid these non-physician practitioners ***more than 80 times*** and ***116 times*** as much as similar non-physician practitioners received from all other pharmaceutical companies combined during the same time period.

186. Confidential witnesses and investigative journalists are not the only ones who have raised concerns over Corcept's apparent bribery and kickback scheme. On December 8, 2021, Corcept disclosed that the United States Attorney's Office for the District of New Jersey had issued a subpoena to Corcept to investigate whether Corcept committed criminal or civil violations with respect to "the sale and promotion of Korlym, ***Corcept's relationships with and payments to health care professionals who can prescribe or recommend Korlym*** and prior authorizations and reimbursement for Korlym."[123] According to Corcept's most recent 10-Q, filed July 29, 2024, the investigation by the United States Attorney's Office is still ongoing.[124]

187. Corcept's unlawful payments to physicians are a material factor that has caused physicians to continue prescribing brand Korlym, and routing their prescriptions to Optime, notwithstanding the availability of Teva's lower-priced generic. Corcept's bribery campaign has accordingly suppressed competition by contributing in material respects to Corcept's overall scheme to deny Teva access to the Korlym market. At the same time, Corcept's bribery campaign has resulted in physicians routing their prescriptions to Optime—where Teva's lower-priced generic Korlym product is not available—which has robbed patients and health plans of the opportunity to

[123] https://ir.corcept.com/static-files/118b8df9-ee90-4c0f-b9cd-dd6c3063bfcb at 2 (emphasis added).

[124] https://ir.corcept.com/static-files/bb343d5b-63fe-4b7e-898d-e42e84c6bfd6 at 25.

choose Teva's lower-priced generic in place of Corcept's more expensive product. Corcept's bribery campaign violates federal and state law, and physician prescribing decisions induced by Corcept's payments elevate physicians' financial interests over their patients' best interests, in violation of physicians' fiduciary duties to their patients. If not for Corcept's bribery campaign, many physicians would write prescriptions that could be filled with Teva's generic, which would result in substantial savings for patients and health plans.

188. Discovery will allow Teva to uncover more details about the operation of Corcept's bribery and kickback scheme. Through discovery, Teva will obtain, among other relevant evidence, the most recent and complete data available on payments made by Corcept and its affiliates to physicians and non-physician practitioners; the most recent and complete data available on the number of prescriptions written by individual prescribers and practice groups over the years; and evidence confirming that a substantial portion of Corcept's payments are in fact illicit bribes and kickbacks that function as compensation for prescribers to continue prescribing brand Korlym notwithstanding the availability of Teva's lower-priced generic.

3. Corcept Continues to Stifle Competition by Entering a New Anticompetitive Exclusive-Dealing Agreement.

189. Since Teva filed this lawsuit in June 2024, Corcept has continued to rely on anticompetitive exclusive-dealing agreements to erect barriers to fair competition and to entrench its monopoly in the market for Korlym, injuring Teva's business and harming patients and their health plans. Further, recent public statements by Corcept have confirmed many of Teva's key allegations—including that the so-called services performed by Optime are illusory, that patients' dependence on Optime has made them far worse off than if Optime were allowed to distribute Teva's generic, and that Optime is firmly entrenched as the key distribution channel without which manufacturers cannot effectively reach Korlym patients.

190. For example, Corcept filed a lawsuit against Optime on October 30, 2025, in the Delaware Court of Chancery, alleging breach of contract and other claims.[125] In its public verified

[125] *Corcept Therapeutics, Inc. v. Optime Care, Inc., et al.*, C.A. No. 2025-1249-KSJM (Del. Ch.).

complaint and related filings, Corcept disclosed that for over a year now, Optime has been unable to fill Korlym prescriptions in a timely manner, and has failed to provide the services Corcept publicly touts. According to Corcept, "[b]eginning in late 2024, … Optime's performance deteriorated significantly," and "Optime repeatedly failed to fulfill patient prescriptions in a timely manner."[126] Optime has been "far too slow to process prior authorization requests from payers," leading to material delays in when patients could "begin treatment."[127] Additionally, Optime has "had insufficient staffing (and insufficiently trained staff) to process" Korlym prescriptions, leading to "long hold times for patients calling the specialty pharmacy, delays in making required outreach to patients, and delays in responding to patient and physician inquiries. Patients reported that, even when they were able to get Optime on the phone, they received poorer quality service, and representatives were often unable to answer important questions."[128] According to Corcept, "Optime's deficient performance has led to inexcusable delays in patients receiving their medication, with wide-ranging consequences," placing patient health in severe jeopardy.[129] Corcept has disclosed that "on any given day, more than 100 patients could be waiting for a late refill because of Optime. Additionally, more than 300 patients who have received prescriptions for Korlym have been waiting for over four weeks for their first shipment."[130]

191. Corcept's complaint also confirms that patients have suffered these inexcusable delays in large part because of Corcept's efforts to entrench its brand monopoly and stifle competition from Teva. According to Corcept, Optime explained that "'[t]he reason for the delays in starting patients on Korlym were the business decisions that Corcept made, ***by demanding to use a branded product*** versus its [authorized] generic product. This caused an increase in workflow for

[126] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Compl. ¶¶ 83-84.

[127] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Compl. ¶ 85.

[128] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Compl. ¶ 85.

[129] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Compl. ¶ 86.

[130] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Corcept Oct. 30, 2025 Mot. to Expedite ¶ 38.

Optime's team, leading to a swell in que [sic] volumes.'"[131] Far from disputing Optime's explanation, Corcept claimed to be "acting well within the discretion afforded to it by the [Corcept-Optime] Agreement in making those decisions," *i.e.*, Corcept's decisions to force Optime to engage in the lengthy and complex insurance approval process so that patients and their health plans would have to pay for Corcept's expensive brand Korlym.[132]

192. The above allegations make clear that the Corcept-Optime exclusive-dealing agreement is anticompetitive and harms not only Teva, but patients as well. If Optime were permitted to dispense Teva's generic product, patients would not need to wait for it to engage in the time-consuming, labor-intensive process of obtaining insurance approval to dispense brand Korlym, or even authorized generic Korlym. Optime could simply dispense Teva's generic, as state substitution laws intend, and patients would receive their medicines for less money and without the delays caused by Corcept's insistence on protecting its monopoly power—and padding its bottom line—by pushing through its more expensive products instead. Teva, and Korlym patients everywhere, have paid a steep price for Corcept and Optime's anticompetitive scheme.

193. The above allegations also confirm that whatever services Optime provides are illusory. Patients have been made worse off as a result of their dependence on Optime—not only because Optime has stood in the way of patients accessing Teva's lower-priced generic product, but also because Optime's deficient performance and delays in filling prescriptions have jeopardized patient health, as Corcept has confirmed. Any purported benefits of Optime's services cannot outweigh those harms to competition and consumers.

194. But rather than alleviating these problems by permitting Optime to dispense Teva's generic product—and engaging in free and fair competition with Teva—Corcept has chosen to double down on its anticompetitive exclusive-dealing strategy by signing up *another* specialty pharmacy and *again* prohibiting that pharmacy from dispensing Teva's generic.

[131] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Compl. ¶ 116 (quoting letter from Optime) (emphasis altered).

[132] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Compl. ¶ 118.

195. On October 1, 2025, Curant announced that it had entered into a pharmacy partnership with Corcept.[133]

196. On October 10, 2025, Corcept terminated the Corcept-Optime agreement.[134] By agreement of Corcept and Optime, the termination is scheduled to become effective on February 5, 2026.[135]

197. Since that time, Teva has reached out to Curant on more than one occasion, with the aim of persuading Curant to dispense Teva's generic product alongside Corcept's products. Curant has refused to engage with Teva, ignoring outreach by email and going so far as to terminate a phone call abruptly as soon as Teva's representative identified himself as a Teva employee. That is despite the fact that Teva is prepared to offer financial terms that would make Curant better off by dispensing Teva's products alongside Corcept's, as opposed to dispensing Corcept's products alone. Curant has never given Teva an explanation for its refusals to entertain offers from Teva, but its conduct strongly suggests that Curant is subject to the same exclusive-dealing restrictions as contained in the Corcept-Optime agreement. Curant's refusal to engage with Teva shows that Curant's agreement with Corcept is not incentive-based, and that Curant does not consider itself free to terminate the agreement in practice.

[redacted]

[133] https://curanthealth.com/curant-rare-announces-pharmacy-partnership-with-corcept-therapeutics/.

[134] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Compl. ¶ 149.

[135] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Ex. A to Nov. 12, 2025, letter from Optime to Chancellor McCormick, at 4-5.

[redacted]

199. Corcept's decision to lock up yet another specialty pharmacy with an exclusive-dealing agreement—notwithstanding this Court's holding that Teva's complaint plausibly alleges the Corcept-Optime agreement has had a substantial foreclosure effect on the relevant market[139]—is a brazen decision to double down on Corcept's anticompetitive tactics, confirming that Corcept cannot succeed through genuine competition on the merits.

200. Nevertheless, according to Corcept's allegations in its lawsuit against Optime, Corcept cannot effectively switch patients to Curant without Optime's help, which Corcept's lawsuit seeks to compel. These allegations confirm Teva's allegation that Optime is the key pharmacy pipeline that is necessary to permit Teva to compete effectively—and that the Corcept-Optime exclusive-dealing agreement has therefore had a substantial foreclosure effect in the market for Korlym.

201. In Corcept's own words, "***Optime is more than a dispenser; it is a critical link between patients and critical medication***."[140] In fact, Corcept has represented that it *cannot* effectively distribute its own products through other pharmacies—including Curant—without Optime's facilitation, and even *with* Optime's facilitation, it will take Corcept up to six months or more to establish Curant as an effective alternative distribution channel.

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[136] [redacted]

[137] [redacted]

[138] [redacted]

[139] *Teva Pharmaceuticals USA, Inc. v. Corcept Therapeutics, Inc. et al.*, No. 5:24-cv-03567-NW (N.D. Cal.), Dkt. 134, at 18-20.

[140] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Corcept Oct. 30, 2025 Mot. to Expedite ¶ 12 (emphasis added).

202. According to Corcept, "Corcept cannot simply pick [an alternative pharmacy] off a list and immediately launch a specialized program supporting thousands of patients. It takes roughly six months to identify the right pharmacy to serve Corcept's patients, and the process of transitioning patient care can take anywhere from three to six months—if everything goes smoothly."[141] Corcept further explained that "switching specialty pharmacies—especially switching a program for Cushing's syndrome, which requires an extensive suite of patient support and education—is not like going down the street to Walgreen's instead of CVS. Corcept's newly contracted pharmacy, and any others it may bring online in the future, must add and then train their staff on Cushing's syndrome, the unique needs of Cushing's syndrome patients, as well as Corcept's program, just as Optime once did."[142]

203. And without Optime's direct involvement, establishing an alternative specialty pharmacy is not possible. According to Corcept, switching patients to a different pharmacy "requires Optime's active participation, including in data transfers, system integration, and patient communications. These responsibilities are largely or exclusively within Optime's control."[143] In fact, according to Corcept, if Optime does not actively assist in setting up an alternative pharmacy, it will "block[] patient access and ***prevent[] any successor pharmacy from serving patients***."[144]

204. Corcept's own words are a powerful validation of Teva's allegations in this lawsuit, because they demonstrate that over the past eight-plus years, Optime has become firmly entrenched as the only practically effective channel for reaching Korlym patients—so much so that any attempt to establish an alternative channel is not practically feasible without Optime's help, even for Corcept. Yet the Corcept-Optime agreement has blocked Teva's access to Optime, thereby making it infeasible for Teva to establish an alternative distribution channel to compete with Corcept.

[141] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Compl. ¶ 50.

[142] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Compl. ¶ 165.

[143] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Corcept Oct. 30, 2025 Mot. to Expedite ¶ 40.

[144] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Corcept Oct. 30, 2025 Mot. to Expedite ¶ 7 (emphasis added).

Teva's inability to reach Korlym patients through alternative channels should come as no surprise in light of Corcept's concession that it cannot do so either, at least not without Optime's help, which has been categorically unavailable to Teva as a result of the Corcept-Optime agreement.

205. By entering into a new exclusive-dealing agreement with Curant, and seeking to compel Optime's help to facilitate the transition, Corcept is aiming to establish Curant as a bulwark to generic competition just like Optime has provided until now. The Corcept-Curant agreement therefore threatens to cause the same anticompetitive effects as the Corcept-Optime agreement has caused, once again blocking patients from accessing Teva's generic mifepristone and protecting Corcept's monopoly from meaningful erosion.

206. Those anticompetitive effects are not lessened by the fact that [redacted] Corcept's explanation that it takes three-to-six months to stand up a new specialty pharmacy—assuming the previous pharmacy actively helps—means that [redacted], Corcept would have enough time to establish yet another pharmacy as a bulwark to generic competition in its place.

207. Moreover, Corcept appears to be taking the position that Optime is forbidden from dispensing Teva's generic product even after the effective date of the termination of the Corcept-Optime agreement. Corcept has alleged broadly that "Section[] 12" of the Corcept-Optime agreement, which contains the exclusivity provision forbidding Optime from distributing competing products, "'shall survive the termination or expiration of [the Corcept-Optime] Agreement for any reason.'"[145]

208. There is no legitimate justification for Corcept to prevent Optime from distributing competing products in perpetuity, even after Optime ceases to perform services for Corcept. Corcept would only try to do so because it knows that Optime has long been the only practically effective channel for reaching Korlym patients, and may remain an effective avenue even after the transition to Curant. Corcept's attempt to continue blocking Teva's access to Optime, in addition to blocking Teva's access to Curant, is further confirmation that Corcept's monopoly position depends on

[145] *Corcept v. Optime*, C.A. No. 2025-1249-KSJM (Del. Ch.), Compl. ¶ 75.

suppressing fair competition by circumventing automatic substitution laws and foreclosing its rivals from accessing the key distribution channels.

VI. CORCEPT'S MONOPOLY POWER AND RELEVANT MARKET

209. The relevant geographic market is the United States, the District of Columbia, and United States territories.

210. The relevant product market is the market for Korlym and its AB-rated generic equivalents.

211. The market for Korlym and its AB-rated generic equivalents is the relevant antitrust market. Direct evidence shows that (a) but for Corcept's conduct, generic versions of mifepristone would have entered the market earlier, at substantially lower prices than brand Korlym; and (b) Corcept never lowered Korlym's prices in response to the pricing of any other actual or potential treatment for endogenous Cushing's syndrome, or anticipated an expected decrease in its Korlym-related revenue following the introduction of generic competition.

212. Korlym is the first FDA-approved medicinal treatment for endogenous Cushing's syndrome. At all relevant times prior to Teva's generic launch, Corcept's share of the relevant market was 100%.

213. Teva launched its generic Korlym in January 2024 with 180-day exclusivity. Despite being the only generic on the market for approximately twenty four months, and despite being priced at a material discount to Corcept's branded product for that entire time, Teva has captured virtually no market share. In fact, on Corcept's first quarter 2024 earnings call on May 1, 2024, Corcept executive Sean Maduck boasted that Corcept was "not aware of losing any patients to generic mifepristone." On Corcept's second quarter 2024 earnings call on July 29, 2024, Maduck again boasted that Teva's generic "has had very little impact on our business" despite being "in the channel for many months." Therefore, even following Teva's generic launch, Corcept still holds a nearly 100% share of the market.

214. Additionally, Corcept has not had to lower its Korlym prices to competitive levels, despite Teva's entry onto the market.

215. Korlym's orphan drug designation is further evidence of Corcept's monopoly power, because orphan drug status is reserved for drugs that treat diseases and conditions that otherwise lack adequate treatments.

216. At all relevant times before and after Teva's launch of generic Korlym, Corcept has possessed the power to exclude competition and/or raise or maintain the price of brand Korlym at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

217. At all relevant times before and after Teva's launch of generic Korlym, a small but significant, nontransitory increase to the price of brand Korlym did not cause (or would not have caused) such a significant loss of sales that the price increase was or would have been unprofitable.

218. Brand Korlym does not exhibit significant, positive cross-elasticity of demand with respect to price with any other pharmaceutical product or treatment for endogenous Cushing's syndrome, as shown by the fact that unit sales of brand Korlym have not gone down despite prices going up, and as further shown by the fact that Corcept has been able to raise prices substantially above marginal cost (at least 77-times marginal cost or higher) without losing so many sales as to make the price increases unprofitable. The ability to profitably raise prices substantially above marginal costs is considered by economists and antitrust courts to be compelling evidence of monopoly power.

219. Brand Korlym is differentiated from all other mifepristone products, and all other endogenous Cushing's syndrome treatments, other than AB-rated generic versions of brand Korlym.

220. Corcept needs to control only brand Korlym (and to stifle competition from its AB-rated generic equivalents), and no other products, in order to maintain the price of brand Korlym profitably at supracompetitive prices. Only free and open competition from AB-rated generic versions of Korlym would render Corcept unable to profitably maintain its prices for Korlym without losing substantial sales.

221. At all material times, high barriers to entry, including regulatory protections, high costs of entry and expansion, and the Corcept-Optime exclusive-dealing agreement, have protected brand Korlym from the forces of price competition.

222. There is direct evidence of monopoly power and anticompetitive effects available in this case sufficient to show Defendants' ability to control the price of Korlym, and/or to exclude relevant competitors, even in the absence of proof of a relevant antitrust market. The direct evidence consists of, *inter alia*, the following facts: (a) generic Korlym would have entered the market at a much earlier date, at a substantial discount to brand Korlym, but for Defendants' anticompetitive conduct; (b) Corcept's gross margin on Korlym (including the costs of ongoing research/development and marketing) at all relevant times was very high; and (c) Corcept never lowered the price of brand Korlym to the competitive level in response to the pricing of other brand or generic drugs.

VII. ANTITRUST IMPACT

223. The intended purpose and effect of Defendants' conduct has been to foreclose or severely limit generic competition to brand Korlym. Defendants' anticompetitive actions have netted Corcept and Optime millions of dollars in revenue at the expense of patients and health insurers (and will do the same for Curant), and to the detriment of Teva as the first generic manufacturer of mifepristone for the treatment of endogenous Cushing's syndrome.

224. As a direct and proximate result of Defendants' unlawful conduct, Teva has been blocked from effectively selling its lower-cost generic product to health plans and patients who have paid monopoly prices for Korlym in the interim. Defendants have continued to charge, and profit, off of Corcept's substantially more expensive branded product because of Defendants' illegal conduct. Particularly: (1) Corcept schemed to delay the approval and launch of Teva's generic through knowingly improper and fraudulent Orange Book listings and sham patent litigation; (2) Defendants have blocked a key distribution channel by entering into long-term exclusive-distribution agreements; and (3) Corcept has made illicit payments to physicians to continue prescribing brand Korlym. The price of brand Korlym, and Corcept's market share, both remain artificially inflated as a result of Defendants' unlawful conduct and Corcept's illicit monopoly. The conduct outlined above was and is exclusionary and an unreasonable restraint on competition.

225. Absent Defendants' conduct, Teva would have entered the market with a lower-cost generic Korlym as early as October 2018, and would have rapidly gained market share and revenue as reliably happens in competitive pharmaceutical markets following generic entry.

226. As a result, Teva has suffered and continues to suffer substantial lost revenue from its inability to capture market share as would be the case absent Defendants' illegal and anticompetitive behavior. The full amount and forms and components of Teva's damages will be calculated after discovery and upon proof at trial, as will the full scope of injunctive relief to which Teva is entitled.

VIII. INTERSTATE AND INTRASTATE COMMERCE

227. Defendants' efforts to monopolize and restrain competition in the market for Korlym and its AB-rated generic equivalents has substantially affected interstate commerce.

228. At all material times, Corcept manufactured, marketed, promoted, distributed, and sold substantial amounts of Korlym in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States, with the assistance of its exclusive-dealing agreement with Optime.

229. At all material times, Corcept transmitted funds, as well as contracts, invoices, and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Korlym, and through its exclusive-dealing agreement with Optime.

230. Defendants' conduct also had substantial intrastate effects in that, among other things, Teva has been prevented from reaching health plans and patients with lower-cost generic mifepristone in each respective state. The continued absence of competition from generic mifepristone for this purpose affects and disrupts commerce within each state.

IX. CONTINUING VIOLATIONS

231. Defendants have engaged in, and continue to engage in, a course of wrongful conduct, including conduct within the applicable limitations periods. Defendants' conduct has inflicted continuing and accumulating harm within the applicable statutes of limitations. Teva accordingly can recover for damages sustained during the applicable limitations periods.

CAUSES OF ACTION

COUNT I: VIOLATION OF 15 U.S.C. § 2

(Against Corcept: Monopolization)

232. Teva repeats and realleges all paragraphs set forth above.

233. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15 and 26, and seeks a judgment that Corcept has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing the relevant market through exclusionary acts.

234. At all relevant times, Corcept possessed and continues to unlawfully possess monopoly power in the relevant market for Korlym and its AB-rated generic equivalents—the power to control prices, prevent falling prices, and exclude competitors such as Teva from the relevant markets. Corcept faces no price constraints and is accordingly able to charge supracompetitive prices for a product that is extremely cheap to produce.

235. Corcept has had a 100% market share from Korlym's launch in 2012 to Teva's generic launch in 2024, and continues to enjoy close to a 100% market share even today, nearly twenty four months after generic entry—all of which demonstrates Corcept's power to exclude competition and supports the conclusion that Corcept has monopoly power. *See, e.g.*, *United States v. Dentsply Int'l, Inc*., 399 F.3d 181, 188 (3d Cir. 2005). ("Dentsply's [75% – 80%] share of the market is more than adequate to establish a prima facie case of [monopoly] power. In addition, Dentsply has held its dominant share for more than 10 years and has fought aggressively to maintain that imbalance.").

236. Corcept willfully and intentionally engaged in an anticompetitive scheme to maintain its monopoly, the components of which either standing alone or in combination (in whole or in part) were designed to and in fact have blocked and delayed entry of generic versions of mifepristone. This scheme included knowingly fraudulent and improper listing of patents in the Orange Book, engaging in sham patent infringement litigation against Teva, maintaining an exclusive distribution agreement with Optime and now Curant, and making illicit payments to physicians as bribes and kickbacks to compensate them for prescribing brand Korlym.

237. During the relevant time periods, Teva has not been afforded the opportunity to compete effectively with Corcept, despite being the only generic manufacturer approved to sell generic mifepristone for endogenous Cushing's syndrome in the United States.

238. Through its overarching anticompetitive scheme, as alleged extensively above, Corcept willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of a superior product, greater business acumen, or historical accident. It thereby injured competition, consumers (including health plans and patients), and Teva throughout the last several years and ongoing into the future.

239. By means of this scheme, Corcept intentionally and wrongfully maintained monopoly power in the market for Korlym and its AB-rated generic equivalents in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. As a result of this unlawful maintenance of monopoly power, Teva has been blocked from competing in the relevant market, and thus lost significant profits and revenue.

240. Teva is entitled to damages and injunctive relief to remedy these injuries.

COUNT II: VIOLATION OF 15 U.S.C. § 2

(Against Corcept: Attempted Monopolization)

241. Teva repeats and realleges all paragraphs set forth above.

242. Corcept attempted to monopolize the market for Korlym and its AB-rated generic equivalents in violation of Section 2 of the Sherman Act based on the anticompetitive conduct described herein.

243. Corcept had a specific intent to monopolize the market for Korlym and its AB-rated generic equivalents. As discussed in more detail above, this scheme included knowingly fraudulent and improper listing of patents in the Orange Book, engaging in sham patent infringement litigation against Teva, maintaining an exclusive distribution agreement with Optime and now Curant, and making illicit agreements with physicians as bribes and kickbacks to compensate them for prescribing brand Korlym. Corcept designed this scheme to, and in fact did, block and delay entry of generic versions of mifepristone for the treatment of endogenous Cushing's syndrome, and

foreclose effective competition after generic entry. In doing so, Corcept attempted to control high prices in the relevant market and to exclude competition.

244. Through the anticompetitive and exclusionary acts described above, Corcept achieved a dangerous probability of success of monopolizing the relevant market. To date, despite the entry of Teva onto the market, Corcept has still maintained its nearly 100% market share and significant pricing power over the market for Korlym and its AB-rated generic equivalents in the United States by blocking Teva from competing effectively.

COUNT III: VIOLATION OF 15 U.S.C. § 1

(Against Corcept and Optime: Conspiracy)

245. Teva repeats and realleges all paragraphs set forth above.

246. This claim arises under the Sherman Act, 15 U.S.C. § 1, and the Clayton Act, 15 U.S.C. §§ 15 and 26, and seeks a judgment that Corcept and Optime have violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by conspiring, combining, and/or agreeing to restrain trade in the relevant markets.

247. Corcept and Optime entered into a long-term exclusive-dealing arrangement that expressly forbids Optime from distributing any products that compete with brand Korlym, including Teva's generic Korlym.

248. This agreement is facially and practically anticompetitive as it restrains competition between Corcept and its competitors, including Teva. This agreement has eliminated any meaningful form of price competition in the market for Korlym and its AB-rated generic equivalents.

249. This exclusive-dealing agreement constitutes an unreasonable restraint of trade under Section 1 of the Sherman Act, 15 U.S.C. § 1.

250. As a direct and proximate result of the Corcept-Optime exclusive-dealing agreement, Teva has been injured in its business or property because it has been blocked from effectively competing in the market, despite the cheaper cost of its equivalent product. All the while, Corcept has enjoyed ill-gotten gains from the overly inflated cost and sales of its branded drug.

251. Teva is entitled to damages and injunctive relief to remedy these injuries.

COUNT IV: VIOLATION OF 15 U.S.C. § 1

(Against Corcept and Curant: Conspiracy)

252. Teva repeats and realleges all paragraphs set forth above.

253. This claim arises under the Sherman Act, 15 U.S.C. § 1, and the Clayton Act, 15 U.S.C. §§ 15 and 26, and seeks a judgment that Corcept and Curant have violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by conspiring, combining, and/or agreeing to restrain trade in the relevant markets.

254. Corcept and Curant entered into a long-term exclusive-dealing arrangement that expressly forbids Curant from distributing any products that compete with brand Korlym, including Teva's generic Korlym.

255. This agreement is facially and practically anticompetitive as it restrains competition between Corcept and its competitors, including Teva. This agreement has eliminated any meaningful form of price competition in the market for Korlym and its AB-rated generic equivalents.

256. This exclusive-dealing agreement constitutes an unreasonable restraint of trade under Section 1 of the Sherman Act, 15 U.S.C. § 1.

257. As a direct and proximate result of the Corcept-Curant exclusive-dealing agreement, Teva has been injured in its business or property because it has been blocked from effectively competing in the market, despite the cheaper cost of its equivalent product. All the while, Corcept has enjoyed ill-gotten gains from the overly inflated cost and sales of its branded drug.

258. The anticompetitive Corcept-Curant agreement threatens substantial loss or damage to Teva's business and property by promising to continue to foreclose Teva from accessing the only effective means of reaching Korlym patients.

259. Teva is entitled to damages and injunctive relief to remedy these injuries.

COUNT V: VIOLATION OF CAL. BUS. & PROF. CODE § 17200

(Against All Defendants: Unfair Competition)

260. Teva repeats and realleges all paragraphs set forth above, except that for the purposes of this Count, Corcept, Optime, and Curant's liability is alleged based *only* upon their unlawful and anticompetitive exclusive agreements regarding the marketing of Korlym for the treatment of Cushing's syndrome and upon Corcept's having made unlawful payments to physicians in connection with the marketing of Korlym. Teva does not allege that any submission that Corcept made to the FDA or any other regulator or that any position Corcept took or statement it made during the patent litigation is the basis for liability under this count.

261. By entering into long-term exclusive-dealing arrangements that expressly forbid Optime and Curant from distributing any products that compete with brand Korlym, including Teva's generic Korlym, and by paying illicit bribes and kickbacks to physicians to induce them to prescribe brand Korlym, Defendants have engaged in unfair competition or deceptive acts and practices in violation of California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to sales of brand Korlym.

262. Defendants' acts were "unlawful" in that they were taken in violation of various laws of the State of California and the United States, including the federal Sherman and Clayton Acts, 15 U.S.C. §§ 1, 2, 15, and 26, California's Cartwright Act, Cal. Bus. & Prof. Code §§ 16720 and 16727, California's prohibition on contracts in restraint of trade, Cal. Bus. & Prof. Code § 16600, California's prohibition on commercial bribery, Cal. Penal Code § 641.3, and California's prohibition of the provision of things of value in exchange for the prescription of drugs covered by insurance, Cal. Ins. Code § 1871.7.

263. Defendants acts were "unfair" in that they threaten an incipient violation of the antitrust laws, violate the policy or spirit of one of those laws because the effects of their acts are comparable to or the same as a violation of the law, and because they otherwise significantly threaten or harm competition.

264. Such unlawful and unfair acts by Defendants have had, and continue to have, a substantial and foreseeable effect on the commerce of California by artificially suppressing competition, and raising prices, for brand Korlym paid for and/or dispensed in California.

265. Such unlawful activities have affected (and continue to affect) both intrastate commerce and interstate commerce flowing into or out of California, and have had (and continue to have) direct, substantial, and reasonably foreseeable effects upon trade and commerce in California.

266. Through either Defendants themselves or agents/contractors they have engaged for the sale of brand Korlym, millions of dollars' worth of brand Korlym has been, and continues to be, sold in California every year.

267. As a direct and proximate result of Defendants' violation of each of the foregoing laws, Teva has been harmed because it has been blocked from effectively competing in the market, despite the cheaper cost of its equivalent product. All the while, Corcept has enjoyed ill-gotten gains from the overly inflated cost and sales of its branded drug.

268. Defendants' conduct in violation of California's Unfair Competition Law was done knowingly, willingly, and flagrantly.

269. Teva is entitled to restitution and injunctive relief to remedy these injuries.

COUNT VI: VIOLATION OF CAL. BUS. & PROF. CODE § 16600

(Against All Defendants: Restraint of Trade)

270. Teva repeats and realleges all paragraphs set forth above.

271. By entering into a long-term exclusive-dealing arrangement that expressly forbids Optime and Curant from distributing any products that compete with brand Korlym, including Teva's generic Korlym, Defendants have violated California's prohibition of contracts in restraint of trade, Cal. Bus. & Prof. Code §§ 16600, *et seq.*, with respect to sales of brand Korlym in California.

272. Such unlawful acts by Defendants have had, and continue to have, a substantial and foreseeable effect on the commerce of California by artificially suppressing competition, and raising prices, for brand Korlym paid for and/or dispensed in California.

273. Such unlawful activities have affected (and continue to affect) both intrastate commerce and interstate commerce flowing into or out of California, and have had (and continue to have) direct, substantial, and reasonably foreseeable effects upon trade and commerce in California.

274. Through either Defendants themselves or agents/contractors they have engaged for the sale of brand Korlym, millions of dollars' worth of brand Korlym has been, and continues to be, sold in California every year.

275. As a direct and proximate result of Defendants' violation of each of the foregoing laws, Teva has been harmed because it has been blocked from effectively competing in the market, despite the cheaper cost of its equivalent product. All the while, Corcept has enjoyed ill-gotten gains from the overly inflated cost and sales of its branded drug.

276. Defendants' conduct in violation of California's prohibition of contracts in restraint of trade was done knowingly, willingly, and flagrantly.

277. Teva is entitled to damages and injunctive relief to remedy these injuries.

COUNT VII: VIOLATION OF VARIOUS STATE ANTITRUST LAWS

(Against All Defendants)

278. Teva repeats and realleges all paragraphs set forth above.

279. In addition to the California laws alleged above, Defendants have violated the following antitrust and competition statutes of multiple states and territories, which are modeled on the Sherman Act:

1. Alaska Stat. §§ 45.50.562, *et seq.* provides a private right of action to any "person who is injured in business or property by a violation of AS 45.50.562–45.50.570…." AS § 45.50.576(a). The Act provides a four-year statute of limitations period, but if the state Attorney General or other state attorney brings an antitrust action based in whole or part on the same conduct, the statute will be tolled for the duration of the action. *Id.* § 45.50.588. Likewise, a claim for a continuing violation is considered to accrue at any time during the period of the violation. *Id.* Defendants violated AS 45.50.562 (combination in restraint of trade) and AS 45.50.564

(monopolization and attempted monopolization) by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the Sherman Act. *See Odom v. Lee*, 999 P.2d 755, 761 (Alaska 2000) (noting "[t]his court is guided by federal Sherman Act cases in construing the Alaska antitrust law… [c]laims brought under AS 45.50.562 are also referred to as Sherman Act § 1 claims; claims under AS 45.50.564 have been termed Sherman Act § 2 claims") (citation omitted).

2. D.C. Code §§ 28-4501, *et seq.* grants a private right of action to "[a]ny person who is injured in that person's business or property by reason of anything forbidden by this chapter." *Id.* § 28-4508. The limitations period for antitrust suits in the District of Columbia is four years from the time the cause of action accrues or one year after the conclusion of any timely action brought by the District of Columbia based in whole or part on any matter complained of in the action, whichever is later. *Id.* § 28-4511. Defendants violated D.C. Code § 28-4502 (combination in restraint of trade) and D.C. Code § 28-4503 (monopolization and attempted monopolization) by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under this provision are identical to the federal claims made in Counts I-IV, *see id*. (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the language of the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations

under federal law. *See Ameritech Corp.,* 21 F. Supp. 2d 27, 45 (D.D.C. 1998) (noting that the "analysis for federal antitrust claims will provide much force" with respect to the District's antitrust provisions because those provisions "essentially track the language" of the Sherman Act); *see also Alemu v. Dep't of For-Hire Vehicles*, 327 F. Supp. 3d 29, 48 n.16 (D.D.C. 2018) (analyzing Sherman Act and D.C. antitrust law regarding monopolization as one because of the consistent statutory language between the two acts).

3. Fla. Stat. §§ 542.15, *et seq.*, provides a private right of action to "[a]ny person who shall be injured in her or his business or property by reason of any violation of § 542.18 or § 542.19…." *Id.* § 542.22(1). The statute provides a four-year statute of limitation period from the time the cause of action accrues. *Id.* § 542.26(1). If the state Attorney General or other state attorney brings an antitrust action for the same conduct, the statute will be tolled for the duration of the action plus one year. *Id.* § 542.26(2). Defendants violated § 542.18 (combination in restraint of trade) and § 542.19 (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of Florida's Antitrust statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See* Fla. Stat. § 542.32 (requiring that "great weight be given to federal precedent in construing analogous provisions of the Florida Antitrust Act"); *see also All Care Nurs. Serv., Inc. v. High Tech Staffing Servs., Inc.*, 135 F.3d 740 (11th Cir. 1998) ("Federal and Florida

antitrust laws are analyzed under the same rules and case law."); *In re Jet 1 Ctr., Inc.*, 332 B.R. 182 (M.D. Fla. 2005) (referring to the Florida Antitrust Act as a "carbon copy" of federal antitrust statutes).

4. Idaho Code §§ 48-101, *et seq.*, provides a private right of action for "[a]ny person injured directly or threatened with direct injury by reason of anything prohibited by this chapter …." *Id.* § 48-113. The act permits recovery of actual damages and treble damages if a court finds a per se restraint of trade violation or an intentional monopolization violation. *Id.* The statute of limitations for private actions is four years after the cause of action accrues or one year after the conclusion of an action brought by the state based in whole or part on any matter complained of in the private action, whichever is later. *Id.* § 48-115 (2). The statute of limitations period is tolled if the court finds defendant fraudulently concealed the events upon which the cause of action is based. *Id.* § 48-115 (3). Defendants violated § 48-104 (combination in restraint of trade) and § 48-105 (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the federal antitrust claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the Idaho Competition Act statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See* Idaho Code §§ 48-101, § 48-102(3) (laying out the harmonization provision which requires that the statute be "construed in harmony with federal judicial interpretations of comparable federal antitrust statutes …").

5. 740 Ill. Comp. Stat. 10/1, *et seq.*, provides a private right of action for any person who has been "injured in his business or property" by a violation of Section 3 of the Act. *Id*. 10/7(2). The Act also permits prevailing plaintiffs to recover treble damages. *Id*. The statute of limitations period is four years, but if the state Attorney General or other state attorney brings an antitrust action based in whole or part on the same conduct, the statute will be tolled for the duration of the action plus one year. *Id.* Defendants violated §3(2) (combination in restraint of trade) and §3(3) (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See* 740 ILCS 10/11 (requiring that "when the wording of [the Illinois Antitrust Act] is identical or similar to that of a federal antitrust law, the courts of this State shall use the construction of the federal law by the federal courts as a guide in construing [the] Act"); *see also Menasha Corp. v. News Am. Mktg. In-Store, Inc.*, 238 F. Supp. 2d 1024 (N.D. Ill. 2003) (treating monopolization, attempted monopolization, and restraint of trade claims under the Illinois Antitrust Act as "identical or similar" to the language of the Sherman Act); *DSM Desotech Inc. v. 3D Sys. Corp.*, 2009 WL 174989, at *6-12 (N.D. Ill. 2009) (holding that plaintiff stated valid claims for attempted monopolization and restraint of trade under the Illinois Antitrust Act because it upheld the same claims made under federal antitrust law).

6. Iowa Code §§ 553.1, *et seq.*, provides a private right of action to any "person who is injured or threatened with injury by conduct prohibited under this chapter" and allows them to bring suit for actual and exemplary damages. *Id.* § 553.12(1)-(3). The statute provides a limitations period of four years after a cause of action accrues, but if the state Attorney General or other state attorney brings an antitrust action based in whole or part on the same conduct, the statute will be tolled for the duration of the action plus one year. *Id*. § 553.16(2). The only specific accrual standard is that if a claim is fraudulently concealed, the statute begins to run within four years after the concealment became known. *Id.* Defendants violated § 553.4 (combination in restraint of trade) and § 553.5 (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing arrangements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See Next Generation Realty, Inc. v. Iowa Realty Co.*, 686 N.W.2d 206, 208 (Iowa 2004) ("In adopting Iowa Code chapter 553, the legislature left us without authority to innovate from the federal courts' understanding of federal antitrust law."); *see also Mahaska Bottling Co. v. PepsiCo Inc.*, 271 F. Supp. 3d 1054, 1080 (S.D. Iowa 2017) (treating plaintiff's Iowa Competition Law claim the same way the court treated plaintiff's federal antitrust claim).

7. Kan. Stat. §§ 50-101, *et seq.*, provides a private right of action to "any person who may be damaged or injured by any agreement, monopoly, trust,

conspiracy or combination which is declared unlawful by the Kansas restraint of trade act … against any person causing such damage or injury." *Id.* § 50-161(b). The statute of limitations for a private action under the Restraint of Trade Act is three years. Kan. Stat. §§ 60-512. Defendants violated § 50-112 (combination in restraint of trade) and § 50-132 (monopolization and attempted monopolization) by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the federal claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute mirror the language of the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See O'Brien v. Leegin Creative Leather Prods., Inc.*, 277 P.3d 1062, 1087 (Kan. 2012) (noting that both "K.S.A. 50-112 and § 1 of the Sherman Act share the 'between persons' language" and therefore looking to federal courts' construction of this language was proper); *Smith v. Phillip Morris Cos.*, 335 P.3d 644, 653 (Kan. Ct. App. 2014) ("[F]ederal precedents interpreting, construing, and applying federal antitrust law can be persuasive authority . . . ."); *see also In re Linerboard Antitrust Litig.*, 223 F.R.D. 335, 351 (E.D. Pa. 2004) (citing Kan. Stat. Ann. § 50-112, among other state antitrust statutes, and stating "the state antitrust statutes on which plaintiffs' claims are based [and] modeled upon or closely track the language of the federal antitrust statutes"). The statute also contains a harmonization provision that requires it to be construed in accordance with the judicial interpretations of federal antitrust law set forth by the U.S. Supreme Court. 2013 Kan. Sess. Laws, ch. 102, § 1(b).

8. Me. Rev. Stat. 10, §§ 1102, *et seq.*, provides a private right of action to any party "injured directly or indirectly in its business or property by any other person or corporation by reason of anything forbidden or declared to be unlawful by [the Act]." *Id*. § 1104. The statute of limitations period for civil antitrust actions in Maine is six years after the cause of action accrues. 14 M. R. S. A. § 752. Defendants violated Me. Rev. Stat. 10 § 1101 (combination in restraint of trade) and Me. Rev. Stat. 10 § 1102 (monopolization and attempted monopolization) of the act by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See McKinnon v. Honeywell Int'l Inc.*, 977 A.2d 420 (Me. 2009) ("We look to both state and federal antitrust law for guidance in the interpretation of the Maine antitrust statute, including the accrual of an antitrust claim"); *DavricMaine Corp. v. Rancourt*, 216 F.3d 143, 149 (1st Cir. 2000) (finding that Maine's antitrust laws "parallel the Sherman Act" and are interpreted in accordance with "the doctrines developed in relation to federal law.").

9. Mass. Gen. L. Ch. 93, §§ 1, *et seq.*, provides a private right of action to "[a]ny person who shall be injured in his business or property by reason of a violation of the provisions of this chapter." *Id.* § 12. The statute allows recovery of actual damages and treble damages if the court finds that the violation was engaged in with malicious intent to injure the person bringing the action. *Id.* The limitations period is four years, but if the state Attorney General or other state attorney brings an antitrust

action based in whole or part on the same conduct, the statute will be tolled for the duration of the action plus one year. *Id*. § 13. Defendants violated § 4 (combination in restraint of trade) and § 5 (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See* Mass. Gen. L. Ch. 93, § 1 (requiring that the antitrust statute be "construed in harmony with judicial interpretations of comparable federal antitrust statutes insofar as practicable"); s*ee Winter Hill Frozen Foods and Servs. v. Häagen-Dazs Co.*, 691 F. Supp. 539, 543 n.5 (D. Mass. 1988) (holding that M.G.L. ch. 93 § 4 should be construed in accordance with Section 1 of the Sherman Act); *West Boylston Cinema Corp. v. Paramount Pictures Corp.*, 2000 Mass. Super. LEXIS 628, at *42 n. 34 (Mass. Super. Ct. 2000) (holding that analysis under M.G.L. ch. 93 §§ 4 and 5 is same as analysis for §§ 1 and 2 Sherman Act claims).

10. Mich. Comp. Laws §§ 445.771, *et seq.*, provides a private right to action to "[any] … person threatened with injury or injured directly or indirectly in his or her business or property by a violation of this act." *Id.* § 445.778(2). The Act allows for recovery of actual damages, or treble damages if the trier of fact finds that the violation was "flagrant." *Id*. The limitations period for private antitrust actions in Michigan is four years from the point the cause of action accrues or one year after the conclusion of an antitrust action brought by the state based in whole or part on any matter complained of in the private action, whichever is later. *Id.* § 445.781.

Defendants violated § 445.771 (combination in restraint of trade) and § 445.773 (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See* Mich. Comp. Laws § 445.784(2) (instructing courts to "give due deference to interpretations given by the federal courts to comparable antitrust statutes"); *see also DXS, Inc. v. Siemens Med. Sys., Inc.*, 991 F. Supp. 859, 865 (E.D. Mich. 1997) ("Courts examining claims under [the Michigan Antitrust] Act apply the same legal analysis as courts examining analogous claims under the Sherman Act"); *see also Partner & Partner, Inc. v. ExxonMobil Oil Corp.*, 2008 WL 896052, at *6 (E.D. Mich. Mar. 31, 2008) (treating plaintiff's restraint of trade claim under the state statute the same as plaintiff's federal restraint of trade claim), *aff'd*, 326 F. App'x 892 (6th Cir. 2009).

11. Mo. Stat. §§ 416.011, *et seq.*, provides a private right of action to "[a]ny person … who is injured in his business or property by reason of anything forbidden or declared unlawful by [the Act]." *Id.* § 416.121. The limitations period for private antitrust actions in Missouri is four years, but if the state Attorney General or other state attorney brings an antitrust action based in whole or part on the same conduct, the statute will be tolled for the duration of the action plus one year. *Id.* § 416.131(2). Defendants violated § 416.031(1) (combination in restraint of trade) and § 416.031(2) (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively blocked (and

threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See Woman's Clinic v. St. John's Health Sys.*, 252 F. Supp. 2d 857, 864 n.3 (finding that "Missouri's antitrust laws are almost identical to the Sherman Antitrust Act, hence the reasoning of all federal antitrust cases will be equally applicable to state claims"); *see also* Missouri Stat. § 416.141 (requiring that the state antitrust statute's provisions be "construed in harmony with ruling judicial interpretations of comparable federal antitrust statutes").

12. Neb. Rev. Stat. §§ 59-801, *et seq.*, provides a private right of action to "[a]ny person who is injured in his or her business or property by any other person or persons by a violation of sections [of the Act], whether such injured person dealt directly or indirectly with the defendant." *Id.* § 59-821. There is no limitations period that applies specifically to antitrust claims in Nebraska. However, the Act requires courts to apply its provisions in accordance with federal antitrust law. *Id.* § 59-829 (stating that when the state antitrust law (the "Junkin Act") uses the same or similar language to a provision of the Sherman Act, "the courts of this state in construing such sections or chapter shall follow the construction given to the federal law by the federal courts"). Because the Act requires courts to apply the Act in accordance with federal antitrust law, the limitations period—along with the accrual and tolling standards—should mirror the federal standard. *See* 15 U.S.C. § 15(b) (specifying a four-year limitations period from the point the cause of action accrues). Defendants violated § 59-801 (combination in restraint of trade) and § 59-802

(monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws. *See* Neb. Rev. Stat. § 59-829 (detailing the harmonization provision); *McDonald Apiary, LLC v. Starrh Bees, Inc.*, 2015 WL 11108873, at *6 n.4 (D. Neb. May 22, 2015) ("Federal authority construing the Sherman Act, 15 U.S.C. § 1 et seq., is authoritative in construing similar provisions of the Junkin Act….").

13. N.M. Stat. §§ 57-1-1, *et seq.*, provides a private right of action to "any person threatened with injury or injured in his business or property, directly or indirectly, by a violation [of the Act]." *Id.* § 57-1-3. The statute of limitations period for antitrust claims in New Mexico is four years, but if the state Attorney General or other state attorney brings an antitrust action based in whole or part on the same conduct, the statute will be tolled for the duration of the action plus one year. *Id.* § 57-1-12(B). Continuing violations are deemed to accrue at any time during the period of the violation. *Id*. *Id.* § 57-1-12(C). Defendants violated § 57-1-1 (combination in restraint of trade) and § 57-1-2 (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the

Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See Singh v. Mem'l Med. Ctr., Inc.*, 536 F. Supp. 2d 1244, 1247 n.3 (D.N.M. 2008) (noting the relevant New Mexico antitrust statute "is patterned after Section 1 of the Sherman Antitrust Act, and mandates a construction 'in harmony with judicial interpretations of the federal antitrust laws'" (quoting N.M. Stat. Ann. § 57-1-15)); *see also, e.g.*, *Gutierrez v. Bean*, 2006 WL 4117064, at *5 (D.N.M. Dec. 13, 2006) ("The NMAA pleading requirements for claims of price fixing, tying and, generally, all claims under the NMAA are the same as those for Sections 1 and 2 of the Sherman Act. Accordingly, for the reasons stated for the dismissal of the federal antitrust claims, Defendant is entitled to dismissal with prejudice of Plaintiffs' antitrust claims brought pursuant to state law.").

14. N.C. Gen. Stat. §§ 75-1, *et seq.*, provides a private right of action to any person injured by reason of any act in violation of the provisions of the statute. § 75-16. Treble damages are to be awarded to a prevailing plaintiff. *Id.* The limitations period for antitrust actions in North Carolina is four years but if the state Attorney General or other state attorney brings an antitrust action based in whole or part on the same conduct, the statute will be tolled for the duration of the action plus one year. *Id.* § 75-16.2. The statute also requires that continuing violations be treated as separate offenses for each week that the violation continues. *Id.* § 75-8. Defendants violated § 75-1 (combination in restraint of trade) and § 75-2.1 (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and

monopolization provisions of the statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See Rose v. Vulcan Materials Co.*, 194 S.E.2d 521, 530 (N.C. 1973) (noting that N.C. Gen. Stat. § 75-1 "was based upon section one of the Sherman Act" and case law interpreting the Sherman Act is "instructive in determining the full reach of [the North Carolina] statute").

15. Ohio R. C. §§ 1331.01, *et seq.*, provides a private right of action to any "person injured in the person's business or property by another person by reason of anything forbidden or …unlawful in those sections, may sue therefor in any court … without respect to the amount in controversy, and recover treble the damages sustained by the person and the person's costs of suit." *Id.* § 1331.08. The limitations period for antitrust actions in Ohio is four years. § 1331.12(B). Defendants violated § 1331.04 by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claim made under these provisions are identical to the Sherman Act claim made in Counts III-IV, *see id.* (¶¶245-59), because the restraint of trade provision of the statute closely mirrors § 1 of the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See Great Lakes Corp. v. Bessemer & Lake Erie R.R.*, 720 N.E.2d 551 (Ohio App. 8 Dist. 1998) (noting that the state antitrust statute is patterned after Sherman Act and has been interpreted in light of federal judicial constructions of Sherman Act); *Johnson v. Microsoft Corp.*, 834 N.E.2d 791 (Ohio 2005) (same); *see also Trane U.S. Inc. v. Meehan*, 563 F.Supp.2d 743, (N.D. Ohio 2008) (applying the continuing violations doctrine to state antitrust claims).

16. Okla. Stat. tit. 79 §§ 201, *et seq.*, provides a private right of action to "[a]ny person who is injured in his or her business or property by a violation of this act." *Id.* § 205(A)(1). The limitations period for antitrust actions in Oklahoma is four years. *Id.* § 205(C). Defendants violated § 203(A) (combination in restraint of trade) and § 203(B) (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See* Okla. Stat. tit. 79 § 212 (requiring that the statute be "interpreted in a manner consistent with Federal Antitrust Law, 15 U.S.C § 1, *et seq.*, and the case law applicable thereto"); *Beville v. Curry*, 39 P.3d 754, 759 (Okla. 2001) (noting that "[t]he provisions of this state's antitrust statutes are similar to federal legislation, and interpretation of federal antitrust legislation provides assistance in interpreting the provisions of the Oklahoma statutes").

17. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, provides a private right of action to "any person injured in his business or property by a violation of this chapter." *Id.* 37-1-14.3. The limitations period for antitrust suits in South Dakota is four years, or one year after the conclusion of a state antitrust action brought by the Attorney General or other state attorney based in whole or part on the same conduct, whichever is later. *Id.* § 37-1-14.4. Defendants violated § 37-1-3.1 (combination in restraint of trade) and§ 37-1-3.2 (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively

blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See Byre v. City of Chamberlain*, 362 N.W.2d 69, 74 (S.D. 1985) ("[B]ecause of the similarity of language between the federal and state antitrust statutes and because of the legislative suggestion for interpretation found in SDCL 37-1-22, great weight should be given to the federal cases interpreting the federal statute."); *see also Assam Drug Co. v. Miller Brewing Co.*, 798 F.2d 311, 313 (8th Cir. 1986) (interpreting a claim under South Dakota's antitrust law by looking to interpretations of federal antitrust law).

18. Va. Code §§ 59.1, *et seq.*, provides a private right of action to "[a]ny person injured in his business or property by reason of a violation of this chapter may recover the actual damages sustained[.]" *Id.* § 59.1-9.12. "If the trier of facts finds that the violation is willful or flagrant, it may increase damages to an amount not in excess of three times the actual damages sustained." *Id.* The limitations period for antitrust suits in Virginia is four years after the cause of action accrues. *Id.* § 59.1-9.14(a). Defendants violated § 59.1-9.5 (combination in restraint of trade) and § 59.1-9.6 (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of

trade and monopolization provisions of the statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See Virginia Vermiculite, Ltd. v. W.R. Grace & Company-Conn.*, 965 F. Supp. 802, 829 (W.D. Va. 1997) (noting that Virginia antitrust claims are governed by the same standard as parallel claims under the Sherman Act); *see also* Va. Code § 59.1-9.17 (requiring that the statute be "applied and construed … in harmony with judicial interpretation of comparable federal statutory provisions").

19. Wa. Rev. Code §§ 19.86.010, *et seq.*, provides a private right of action to "[any] person who is injured in his or her business or property" by a violation of the act. *Id.* § 19.86.090. The limitations period for antitrust suits in Washington is four years from the point the cause of action accrues. *Id.* § 19.86.120. Defendants violated § 19.86.030 (combination in restraint of trade) and § 19.86.040 (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See Murray Publ'g Co. v. Malmquist*, 832 P.2d 493, 497 n.4 (Wash. Ct. App. 1992) (observing that § 19.86.030 is nearly identical to § 1 of the Sherman Act); *Rowan Nw. Decorators v. Wash. State Convention & Trade Ctr.*, 898 P.2d 310, 314 n.14 (Wash. Ct. App. 1995) ("The [Act's] prohibition on monopolies is patterned after and contains nearly identical language to the federal Sherman Antitrust Act…[.]").

20. W.Va. Code §§ 47-18-1, *et seq.*, provides a private right of action to "[a]ny person who shall be injured in his business or property by reason of a violation of the provisions of this article." *Id.* § 47-18-9. The limitations period for antitrust suits in West Virginia is four years, and a continuing violation is deemed to accrue at any time during the period of the violation. § 47-18-11. Defendants violated § 47-18-3 (combination in restraint of trade) and § 47-18-4 (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See Kessel v. Monongalia Cnty. Gen. Hosp. Co.*, 648 S.E.2d 366, 374 (W. Va. 2007) (explaining that West Virginia law directs courts to apply federal decisional law interpreting the Sherman Act to West Virginia's own parallel antitrust statute).

21. Wis. Stat. §§ 133.01, *et seq.*, provides a private right of action for "any person injured, directly or indirectly, by reason of anything prohibited by this chapter." *Id.* § 133.18(1)(a). The limitations period for antitrust suits in Wisconsin is six years after the cause of action accrued. *Id.* § 133.18(2). Defendants violated § 133.03(1) (combination in restraint of trade) and § 133.03(2) (monopolization and attempted monopolization) of the Act by entering into unlawful exclusive dealing agreements that effectively blocked (and threaten to block) meaningful generic competition for Korlym nationwide, and by paying kickbacks to physicians to induce brand Korlym prescriptions. TAC (¶¶136-67, 189-209); (¶¶168-88). The claims

made under these provisions are identical to the Sherman Act claims made in Counts I-IV, *see id.* (¶¶232-59), because the restraint of trade and monopolization provisions of the statute closely mirror the Sherman Act and should be applied in a manner consistent with federal antitrust laws, including the tolling and accrual standards applicable to the statute of limitations under federal law. *See Conley Publ'g Grp., Ltd. v. J. Commc'ns, Inc.*, 665 N.W.2d 879, 885-86 (Wis. 2003) ("[T]he construction of [the Wisconsin Antitrust Act] is controlled by federal decisions under the Sherman Act." (citation omitted)), *abrogated on other grounds* by *Olstad v. Microsoft Corp.*, 700 N.W.2d 139 (Wis. 2005); *see also Roumann Consulting Inc. v. Symbiont Constr., Inc.*, 2019 WL 3501527, at *11 (E.D. Wis. Aug. 1, 2019) (finding that "Wisconsin courts construe [§ 133.01(1)] in conformity with federal cases decided under the Sherman Act").

280. Such unlawful acts by Defendants have had, and continue to have, a substantial and foreseeable effect on the commerce of the states and territories whose laws are recited above, by artificially suppressing competition, and raising prices, for brand Korlym paid for and/or dispensed in each of those states and territories.

281. Such unlawful activities have affected (and continue to affect) both intrastate commerce and interstate commerce flowing into or out of the states and territories whose laws are recited above, and have had (and continue to have) direct, substantial, and reasonably foreseeable effects upon trade and commerce in each of the states and territories whose laws are recited above.

282. Through either Defendants themselves or agents/contractors they have engaged for the sale of brand Korlym, millions of dollars' worth of brand Korlym has been, and continues to be, sold in the states and territories whose laws are recited above every year.

283. As a direct and proximate result of Defendants' violation of each of the foregoing laws, Teva has been harmed because it has been blocked from effectively competing in the market, despite the cheaper cost of its equivalent product. All the while, Corcept has enjoyed ill-gotten gains from the overly inflated cost and sales of its branded drug.

284. Defendants' conduct was done knowingly, willingly, and flagrantly.

285. Teva is entitled to damages and injunctive relief to remedy these injuries.

PRAYER FOR RELIEF

WHEREFORE, Teva prays that the Court:

286. Enter judgment against Defendants and in favor of Teva;

287. Award Teva actual, consequential, compensatory, treble, punitive, and/or other damages, in an amount to be proven at trial, including pre- and post-judgment interest at the statutory rates;

288. Enter an injunction invalidating the exclusive-dealing arrangements between Corcept and Optime, and between Corcept and Curant, and any other practices by Defendants that effectively and unlawfully stifle competition; and

289. Award such further and additional legal and equitable relief as is necessary to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, as the Court may deem just and proper under the circumstances.

DEMAND FOR JURY TRIAL

290. Teva demands a jury trial on all claims so triable under Federal Rule of Civil Procedure Rule 38(b).

Dated: January 14, 2026

Respectfully submitted,

By: */s/ Michael Shipley*

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